UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE AMITIZA ANTITRUST LITIGATION This Document Relates to: *All Actions*	Civil Action No. 1:21-cv-11057-MJJ **REDACTED PUBLIC VERSION** **REQUEST FOR LEAVE TO FILE UNDER SEAL FORTHCOMING**

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively "Takeda") submit this memorandum supporting their Motion for Summary Judgment for all of Plaintiffs'[1] claims.

INTRODUCTION

In September 2014, Par Pharmaceutical, Inc. ("Par") entered into a settlement agreement resolving then ongoing and potential future patent litigation[2] with Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., ("Takeda"), Sucampo Pharmaceuticals, Inc. ("Sucampo"), and R-Tech Ueno, Ltd. ("RTU") involving Sucampo's Amitiza[3] product (the "2014 Par Settlement," the "Settlement Agreement" or the "Agreement").[4] Under the Agreement, [redacted] of Par's profits on sales of its generic [redacted] —nearly seven years

[1] This motion covers issues common to all cases, so the term "Plaintiffs" includes FWK Holdings, LLC, Meijer, Inc., and Meijer Distribution, Inc. (collectively, the "direct purchaser plaintiffs" or "DPPs"), Premera Blue Cross and other similarly situated third-party payers (collectively, the "end purchaser plaintiffs" or "EPPs"), Walgreens Co., The Kroger Co., Albertsons Companies, Inc. and H-E-B, L.P., and CVS Pharmacy, Inc. (collectively, the "Retailers").

[2] *Sucampo AG, et al v. Anchen Pharms. Inc.*, No. 1:13-cv-00202-GMS (D. Del.) (the "Par Patent Litigation"). The settlement terms are set forth in a Settlement & License Agreement, dated September 30, 2014. *See* supporting Declaration of Joshua S. Barlow, Ex. 13 (2014 Par Settlement). Subsequent exhibits to the Barlow Declaration are cited as "Ex. #." Attached as Exhibit B to the 2014 Par Settlement is a Manufacturing and Supply Agreement between Sucampo and Par (the "Sucampo-Par AG Supply Agreement").

[3] Amitiza® is a lubiprostone drug. Sucampo holds the New Drug Application ("NDA") for it in the United States.

[4] Ex. 13 (2014 Par Settlement). Par, Sucampo, and RTU are not parties to this litigation. Sucampo (now Mallinckrodt) owns the patents that were at issue in the Par Patent Litigation and licensed them and others to Takeda, which then marketed and sold brand Amitiza in the United States pursuant to a Collaboration and License Agreement ("CLA") with Sucampo, dated October 29, 2004. Ex. 5 (CLA). Takeda cannot sublicense its rights to third parties without Sucampo's consent. *Id.* at § 2.3. Takeda purchases brand Amitiza from RTU for resale. See Ex. 5 (CLA), Recitals. Both Mallinckrodt and Par are in, or have recently emerged from, bankruptcy. SOF ¶ 14.

[5] [redacted]

[6] An AG is a generic pharmaceutical product that is sold under the brand's NDA, as opposed to a generic manufacturer's ANDA. *Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 416 n.4 (3d Cir. 2013) (citing 21 U.S.C. § 355(t)(3)). Thus, a generic manufacturer selling an AG does not need FDA approval of its ANDA to do so.

before the expiration of several patents covering Amitiza listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication (the "Orange Book").[7]

Five other generics ("Later Filers" and with Par, "ANDA Filers") filed ANDAs. Sucampo, RTU, and Takeda sued each for patent infringement.[8] [redacted].[9]

FDA had not approved Par's ANDA product by January 2021 when Par was licensed to enter the market under the Settlement Agreement. As a result, Par exercised its option to market a Sucampo-supplied Amitiza AG and has done so since that time.[10] Several of the Later Filers launched their generic Amitiza (either an AG or an ANDA product) shortly after January 1, 2023.[11]

Plaintiffs allege that the Agreement improperly delayed the entry of generic competition to brand Amitiza because it contained a so-called "reverse payment"[12] that induced Par to settle for a later licensed entry date than it otherwise would have. Plaintiffs assert three, sometimes conflicting, reverse payment theories: (1) that the Agreement's declining royalty provision disincentivized Sucampo and Takeda from launching an AG in competition with Par because it would lower the royalty Sucampo would receive from Par, and therefore resulted in a *de facto*

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[7] Under the Hatch-Waxman Act, a brand manufacturer with an approved NDA is required to list in a publication known as the Orange Book any patents that cover its approved drug product or an approved method of using that product. *See Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citing 21 U.S.C. §§ 355(b)(1), (c)(2)).

[8] Ex. 14 (Dr. Reddy's Patent Litigation Docket Sheet, Nov. 12, 2014 - Nov. 21, 2016), TAKAMI1210137-46; Ex. 15 (Amneal Patent Litigation Docket Sheet, Apr. 13, 2017 - Sept., 19, 2018); Ex. 16 (Teva Patent Litigation Docket Sheet, Sept. 25, 2017 - Sept. 19, 2018); Ex. 17 (Sun Patent Litigation Docket Sheet, Oct. 30, 2018 - July 1, 2020); Ex. 18 (Zydus Patent Litigation Docket Sheet, Jan. 28, 2020 - Nov. 13, 2020).

[9] Ex. 21 (Sept. 14, 2016 Dr. Reddy's Settlement TAKAMI0001697); Ex. 22 (June 28, 2018 Teva Settlement TAKAMI1129172); Ex. 23 (June 28, 2018 Amneal Settlement); Ex. 24 (June 4, 2020 Sun Settlement); Ex. 25 (Oct. 21, 2020 Zydus Settlement).

[10] [redacted] Ex. 13 (2014 Par Settlement) § 3.1; Ex. B to 2014 Par Settlement (Sucampo-Par AG Supply Agreement).

[11] Plaintiffs have not alleged and have produced no evidence—either factual or expert—that shows that any of the settlement agreements with the Later Filers were anticompetitive in any way.

[12] A "reverse payment" in this context is alleged to be a payment from the brand (patent holder) to the generic (alleged infringer) in a situation where a payment should go from the generic (alleged infringer) to the brand (patent holder).

agreement by Sucampo and Takeda not to launch a second AG, allowing Par to enjoy higher profits; (2) that the Agreement's provision requiring Par to pay Sucampo 50% of its profits on sales of Par's generic, irrespective of any decline, was so *high* (in favor of Sucampo) that it disincentivized Sucampo and Takeda from launching a second AG, allowing Par to enjoy higher profits; and (3) that the 50% royalty on Par's Amitiza AG sales was so *low* (in favor of Par), versus a "typical" royalty in AG license agreements, that it resulted in a "payment" inducing Par to settle for a later licensed entry date.

Plaintiffs claim that "but for" any one of these three reverse payments, Par would have entered the market with its own ANDA product earlier than January 2021, at different times depending on different "scenarios"[13]:

[redacted]

Plaintiffs' claims fail for at least the following reasons:

1. **Par's 50% royalty to Sucampo on Par's AG sales does not decline.** Plaintiffs' first "reverse payment" theory—that a declining royalty disincentivized Sucampo and Takeda from launching a second AG in competition with Par's Sucampo-supplied AG product misreads the Agreement. The Agreement's unambiguous terms provide that its royalty rate decline triggers *do not apply* when Par distributes an AG product, as Par did here. Instead, the royalty remains at 50%, irrespective of Sucampo and Takeda launching a second AG. Without a decline, there was

[13] All of Plaintiffs' scenarios are predicated on Par getting its own ANDA product approved by FDA and launching it into the market. *See* Ex. 75A (Clark Report) ¶ 15.

no AG-launch disincentive by virtue of the Agreement, and therefore no reverse payment.

2. **Par's 50% royalty to Sucampo is not "too high."** Plaintiffs' second "reverse payment" theory—that the 50% royalty was itself high enough (irrespective of any decline) to keep Sucampo and Takeda from launching a second AG because Sucampo would earn more from collecting the royalty than by launching a competing product—describes a typical patent litigation settlement that is not actionable as a reverse payment under *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). It does not give rise to an inference that Par's entry date was later than it would have been; "a generic company may pay a royalty to the brand to gain an earlier entry date than it would get by compromising on the date alone."[14]

3. **Par's 50% royalty to Sucampo is not "too low."** Plaintiffs' third and contradictory "reverse payment" theory is that the 50% royalty was too *low*, thereby improperly compensating Par to delay entry.[15] But where the payment flows from the generic to the brand, a royalty alone—regardless of rate—cannot by itself be actionable as a matter of law. As the Supreme Court explained in *Actavis*, a brand manufacturer can lawfully settle Hatch-Waxman litigation by "allowing the generic manufacturer to enter the patentee's market before the patent expires," without requiring any royalty. 570 U.S. at 139. If such a settlement does not violate the antitrust laws, a settlement that requires a payment *from* the generic *to* the brand cannot either.

4. **Plaintiffs lack further evidence of an anticompetitive agreement.** Plaintiffs in antitrust cases must produce evidence that is not only consistent with conspiracy, but "tends to

[14] Ex. 206 (2011 FTC Report) at 141 n.4.

[15] Needless to say, Par's royalty rate cannot simultaneously be both too high, as DPPs' expert Ruhm opines (*see* Ex. 94B (Ruhm Rebuttal) ¶¶ 44-47), and too low, as Retailers' expert Leffler opines (Ex. 84B (Leffler Rebuttal), ¶¶ 67-71). It is black-letter law that a party cannot submit conflicting facts on the same issue to defeat summary judgment. *See, e.g., Faircloth v. United States*, 837 F. Supp. 123, 127 (E.D.N.C. 1993) ("[P]laintiffs cannot create an issue of material fact in order to defeat summary judgment by presenting conflicting testimony among their own witnesses.").

exclude the possibility of independent action."[16] Plaintiffs lack any direct evidence that Sucampo and Takeda entered into an anticompetitive agreement with Par, given the unambiguous terms of the Agreement, and Plaintiffs lack any indirect evidence that tends to exclude the possibility of Sucampo and Takeda retaining their AG-launch rights.

5. **Takeda does not have market power or monopoly power in the relevant market.** Plaintiffs must prove that Takeda possessed "market power" (Section 1 claim) or "monopoly power" (Section 2 claim) in a properly defined market. Here, Plaintiffs' best case is that Takeda's share of the relevant market is less than 30% throughout the relevant time period, which is too low to show either market power or monopoly power as a matter of law.

6. **Plaintiffs' "but for" scenarios ignore patents covering Amitiza**. It is undisputed that patent clearance was a prerequisite for Par to launch its ANDA product. But simply winning the Par Patent Litigation would not have given Par clearance. Sucampo asserted seven patents against Par's ANDA products. At the time of settlement, two additional patents covering Amitiza had issued, were set to expire as late as 2027, and were listed in the Orange Book, but had yet to be asserted against Par. Thus, Par would have needed to clear these *additional* Orange Book patents, likely via *a second* Hatch-Waxman litigation, before it could launch its generic Amitiza. Par was aware of these newly-issued patents and accounted for them in the Agreement. They are *not*, however, accounted for in Plaintiffs' "but for" scenarios, meaning that Plaintiffs have failed to develop evidence that Par could have lawfully launched its generic Amitiza product before January 1, 2021.

7. **Par's ANDA was not approved by January 1, 2021, when Par began distributing its Sucampo-Supplied Amitiza AG**. The Agreement delayed nothing. FDA did not

[16] *Monsanto Co. v. Spray-Rite Serv. Corp.,* 465 U.S. 752, 764 (1984); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

approve Par's ANDA product until June 2022—more than one year *after* the licensed entry date when Par began distributing an Amitiza AG. Thus, for reasons independent of the Agreement, Par could not have entered the market with its own generic Amitiza by any of Plaintiffs' assumed launch dates in Scenarios 1-3. Plaintiffs speculate that Par stalled its efforts to obtain FDA approval post-settlement, but Plaintiffs have no evidence supporting that theory. It is also directly contradicted by the potential for Par's accelerated entry under the Agreement and the potential for it to pay a lower (or zero) percent royalty on sales of its own ANDA product. Instead, Plaintiffs rely exclusively on their own experts' unsupported and inadmissible opinions about Par's and FDA's intentions and state of mind. Because Plaintiffs cannot show that Par would have entered the market before January 1, 2021 absent the Agreement, Plaintiffs cannot prove that the Agreement delayed generic entry or caused any antitrust injury.

8. **There is no evidence that the ANDA Filers were launch ready at the times Plaintiffs assume.** While Plaintiffs allege that Par's ANDA would have received FDA approval by certain dates prior to January 1, 2021, they present no evidence at all that any of the ANDA Filers would have been able to actually launch their own products at the times assumed in Plaintiffs' Scenarios 1-3. Plaintiffs' production expert (who offers blanket, generalized, and conclusory opinions that the ANDA Filers could have launched earlier than January 1, 2021), admits that launching a drug like generic Amitiza requires, among many other things, reliable access to the required materials, unique technical know-how, and manufacturing capacity, but offers no evidence on any of these topics. Moreover, Plaintiffs have no evidence that any of the ANDA Filers were ready and able to launch their ANDA products by the dates Plaintiffs' but-for scenarios assume. All Plaintiffs rely upon are the inadmissible opinions of their production expert.

9. **At least twenty-three proposed class members have no claims.** The proposed

direct purchaser class definition includes thirteen members who purchased only AG product from third parties during the class period. These proposed class members are not "direct purchasers" under *Illinois Brick*, and have no standing to pursue federal antitrust claims. The proposed direct purchaser class definition also includes ten members who purchased only brand Amitiza during the class period, even when generic Amitiza became available at a lower price. Plaintiff have provided no basis to assume that these ten proposed class members would have purchased generic Amitiza in the "but for" world, and therefore suffered no injury-in-fact and have no claim.

10. **The statute of limitations limits Plaintiffs' damages.** Plaintiffs concede that press releases contemporaneous with the Agreement implied that the profit split under the Agreement was 50% to Par and 50% to Sucampo.[17] To the extent Plaintiffs rely on a theory that this profit split, irrespective of any royalty decline, was a reverse payment, Plaintiffs were (or should have been) aware of any claim they may have had back in 2014. Thus, the onset of their alleged damages can extend no further back than four years preceding the filing of their Complaints.

For these reasons, the Court should grant summary judgment and dismiss Plaintiffs' claims.

REGULATORY FRAMEWORK

A company seeking to sell a branded pharmaceutical product in the U.S., such as Amitiza, must first obtain FDA approval of its NDA.[18] Upon approval, the company also must list any patents it contends cover the branded product in FDA's "Orange Book."[19]

Under the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), a company seeking to sell its own generic version of a brand drug in the U.S. must obtain

[17] All royalties went to Sucampo. Takeda received no payments under the Agreement. *See* 13 (2014 Par Settlement) § 3.13(a).
[18] 21 U.S.C. §§ 355, *et seq.*
[19] 21 C.F.R. § 314.53.

FDA approval of an ANDA.[20] To do so, the generic manufacturer must demonstrate bioequivalence of the generic version to the listed referenced brand drug (the "RLD") and satisfy many other requirements imposed by FDA.[21] The ANDA must also include a certification regarding the patent status of the RLD.[22] If the ANDA applicant seeks to market a generic drug prior to expiration of a patent listed for the brand drug in the Orange Book, it must submit a "Paragraph IV certification" asserting that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug[.]"[23] The ANDA applicant must give notice of the certification to the brand company.[24]

The filing of a Paragraph IV certification is, by statute, an act of patent infringement, allowing the patent holder to sue.[25] If a patent holder brings suit within 45 days of receiving a Paragraph IV certification, FDA cannot grant final approval of the related ANDA for 30 months absent a final court decision holding that the patents are invalid or not infringed.[26]

Critically, expiration of the 30-month litigation stay does not automatically give rise to final ANDA approval, but simply lifts the prohibition against FDA from doing so.[27] Only if FDA approves an ANDA can the ANDA filer launch its generic product. If the ANDA filer receives FDA approval and launches its generic product while patent litigation is pending, it does so "at risk," because it may be enjoined from selling the product and liable for infringement damages should it ultimately lose the patent litigation.[28]

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[20] 21 U.S.C. § 355(a). In the case of an AG, the corresponding NDA must be FDA-approved. 21 U.S.C. § 355(t)(3).
[21] *See* 21 U.S.C. § 355(j).
[22] 21 U.S.C. § 355(j)(2)(A)(vii).
[23] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[24] 21 U.S.C. § 355(j)(2)(B).
[25] 35 U.S.C. § 271(e)(2).
[26] *See* DPP Compl., ECF No. 28, ¶ 66; 21 U.S.C. § 355(j)(5)(B)(iii).
[27] *Cf. Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.*, No. 18-1994, 2021 WL 3144897, at *5 (D.N.J. July 26, 2021).
[28] SOF, ¶ 10; Ex. 86 (Liu Report) ¶ 43; Ex. 91 (Mehes Report) ¶ 59; *see also Mylan Inc & Subsidiaries v. Comm'r of Internal Revenue*, 76 F.4th 230, 243 (3d Cir. 2023).

Under the Hatch-Waxman Act, the first Paragraph IV ANDA filer has the right to market the generic without competition from any other ANDA filer for 180 days. FDA cannot approve other, later-filed ANDAs until the first-filer's 180-day exclusivity has run or been forfeited.[29] This 180-day first-filer marketing exclusivity period does not apply to, or bar the sale of, an AG version of the brand product that is made and sold or licensed by the owner of the brand product.

FACTUAL BACKGROUND[30]

In 2006, FDA approved Sucampo's NDA for Amitiza, a medication indicated for the treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in adult women (as of 2008), and opioid-induced constipation in adults (as of 2013).[31] Sucampo secured patents that covered Amitiza, granting Sucampo the right to exclude others from manufacturing and marketing generic Amitiza until the last patent expires in 2027.[32] Sucampo listed each of those patents in the Orange Book.[33] Takeda markets and sells brand Amitiza in the United States pursuant to the CLA with Sucampo.[34]

In February 2010, Anchen Pharmaceuticals, Inc. ("Anchen") submitted an ANDA seeking approval of a generic Amitiza product.[35] FDA initially rejected Anchen's ANDA in August 2010.[36] FDA directed Anchen to comply with FDA's August 2010 draft guidance regarding recommended bioequivalence testing, conduct additional clinical studies, and submit a revised ANDA.[37] In

[29] 21 U.S.C. § 355(j).
[30] This section contains a broad overview of the facts for context. A more detailed statement of material, undisputed facts (the "SOF") will be filed by Takeda under L.R. 56.1 and the Court's Standing Orders. Those facts are discussed in the sections of the brief that rely upon them.
[31] SOF, ¶ 5.
[32] SOF, ¶¶ 12, 70.
[33] Pub. L. 98–417, 98 Stat. 1585 (1984); DPP Compl., ECF No. 28, ¶ 160.
[34] Ex. 4 (Feb. 25, 2007, "Takeda and TAP to Promote Sucampo's Amitiza® in the United States").
[35] DPP Compl., ECF No. 28, ¶ 172.
[36] DPP Compl., ECF No. 28, ¶¶ 174, 182.
[37] DPP Compl., ECF No. 28, ¶¶ 174-175, 182.

November 2011, Par acquired Anchen and the rights to the Amitiza ANDA.[38] In 2012, Par submitted a revised ANDA, which FDA accepted.[39] Par's revised ANDA contained a Paragraph IV certification as to all Amitiza patents then-listed in the Orange Book, certifying that they were either invalid or not infringed by Par's product.[40] The certification triggered Sucampo's right to sue Par, which it, joined by Takeda, did in February 2013.[41]

In September 2014, after nineteen months of litigation, the parties entered into a settlement agreement. The Agreement granted [redacted].[43] The license gave [redacted].[44]

Par agreed to pay a royalty to Sucampo in exchange for the license, but the structure and amount of that royalty differed based on whether Par distributed an AG or its own ANDA product. [redacted].[45]

[redacted]

[38] DPP Compl., ECF No. 28, ¶ 186.
[39] Ex. 8 (Par Paragraph IV Certification).
[40] Ex. 9 (Par PIV Notice Letter, Dec. 26, 2012): Ex. 10 (Par PIV Notice Letter, Jan. 24, 2013); Ex. 11 (Par PIV Notice Letter, May 7, 2013).
[41] Ex. 12 (Par Patent Litig., Compl.).
[42] Sucampo asserted seven patents in the Par Patent Litigation, and the settlement gave a license to Par for those seven patents *and* two additional patents that issued during the litigation. Ex. 19 (Par Patent Litig., Am. Compl.), ¶¶ 26-30, 36-44. Because of the settlement, those two later-issued patents were never asserted against Par, but were asserted against the Later Filers. Ex. 20 (Teva Patent Litig., Compl.), ¶¶ 15, 51-58.
[43] Ex. 13 (2014 Par Settlement) § 3.1.
[44] Ex. 13 (2014 Par Settlement) §§ 3.1, 3.12.
[45] Ex. 13 (2014 Par Settlement) § 3.13(a).

[redacted][46]

Thus, Par's royalty obligation would decline only if Par distributed its own ANDA product—it would not decline if Par distributed a Sucampo-supplied AG.

The Agreement [redacted][47] Specifically, as Plaintiffs concede, the Agreement provided:

[redacted][48]

[redacted][49]

At the time of the Agreement, FDA had yet to approve Par's ANDA.[50] Indeed, FDA had not even given "tentative approval" to Par's ANDA—FDA's initial determination that an ANDA has met the requirements for approval, subject to any additional review.[51] FDA did not finally approve Par's ANDA until June 27, 2022, over one year *after* Par began distributing Amitiza AG under the Agreement.[52] Plaintiffs have tried—and failed—to prove that anything would have been different in the absence of the challenged conduct—*i.e.*, that Par would have received final FDA

[46] Ex. 13 (2014 Par Settlement) § 3.13(a)-(c).
[47] Ex. 13 (2014 Par Settlement) § 3.14.
[48] DPP Compl., ECF No. 28, ¶ 248.
[49] Ex. 13 (2014 Par Settlement) § 3.14.
[50] *See* 21 U.S.C. § 355(a); DPP Compl., ECF No. 28, ¶ 240.
[51] *See id.*; *see also Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1360 & n.1 (Fed. Cir. 2015) (citing 21 U.S.C.§ 355(j)(5)(B)(iv)(II)(dd)(AA)). Regardless, tentative approval alone would not have been enough. *See Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 859 (D.C. Cir. 2008) ("Nor does [tentative approval] guarantee final approval, which may depend upon an 'additional review of the application by FDA.'" (quoting 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA))).
[52] SOF ¶ 186; *see also* Ex. 26 (Orange Book: Product Details for ANDA 201442, Nov. 11, 2024).

approval and launched earlier (using its ANDA product) but for the Agreement.

Pursuant to the Agreement, Par was lawfully able to market generic Amitiza without FDA approval of its ANDA and six years before the expiration of Sucampo's patents in 2027.[53] Par began distributing an Amitiza AG product in January 2021 and continues to do so.[54] Pursuant to their own settlement agreements with Sucampo and Takeda, several of the Later Filers launched their generic Amitiza products (AG or ANDA) shortly after January 1, 2023.[55]

STANDARD OF REVIEW

To avoid summary judgment, Plaintiffs "must establish that there is a genuine issue of material fact as to whether [Defendants] entered into an illegal conspiracy that caused [plaintiffs] to suffer a cognizable injury." *Matsushita*, 475 U.S. at 585-86.[56] "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat . . . summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphases in original).[57]

"[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Plaintiffs' evidence must be "significantly probative," not "merely colorable." *Anderson*, 477 U.S. at 249-50. Indeed, "[g]enuine issues of material fact are not the stuff of an opposing party's dreams. On issues where the nonmovant bears the ultimate burden of proof, he must present definite,

[53] Ex. 13 (2014 Par Settlement) § 1.1 ("License Effective Date" of January 1, 2021), § 3.1.
[54] SOF ¶¶ 28, 177.
[55] SOF ¶¶ 189, 193, 198.
[56] *See also RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 11-15 (1st Cir. 2001).
[57] *See also In re Nexium*, 42 F. Supp. 3d 231, 248 (D. Mass. 2014), *aff'd*, 842 F.3d 34 (1st Cir. 2016).

competent evidence to rebut the motion." *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991).[58] "[C]onclusory allegations, improbable inferences, and unsupported speculation," will not suffice. *Nexium*, 42 F. Supp. 3d at 273.[59]

Adhering to the summary judgment standard is critical where, as here, Plaintiffs rely almost exclusively upon expert opinions. "[A]n expert's opinion is not a substitute for a plaintiff's obligation to provide evidence of facts that support the applicability of the expert's opinion to the case," *Virgin Atl. Airways Ltd. v. Brit. Airways PLC*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999), *aff'd*, 257 F.3d 256 (2d Cir. 2001), because expert testimony "without . . . a factual foundation cannot defeat a motion for summary judgment." *Nexium,* 42 F. Supp. 3d at 248 (citation omitted).

ARGUMENT

I. THE UNDISPUTED FACTS DEMONSTRATE NO REVERSE PAYMENT

In *FTC v. Actavis, Inc.*, the Supreme Court addressed a settlement that "require[d] the patentee to pay the alleged infringer, rather than the other way around." 570 U.S. at 141. The Court held that a settlement of Hatch-Waxman patent litigation providing for a large and unjustified "reverse" payment from the patentee to the accused infringer is subject to scrutiny under the antitrust "rule of reason." *Id.* at 158-60. The Court acknowledged, however, that it is not uncommon for the accused ***infringer*** to pay money to the ***patent holder*** as part of the settlement, and confirmed that its decision did not alter the understanding that a settlement with a payment in this "familiar" direction is ***not*** subject to antitrust liability. *Id.* at 158. Indeed, Plaintiffs concede that in a "normal patent settlement," the money flows in that direction: "the company accused of

[58] *See also LeBlanc v. Great Am. Ins. Co.*, 6 F.3d 836, 841-42 (1st Cir. 1993) (evidence presented by non-moving party "cannot be conjectural or problematic; it must have substance in the sense that it limns differing versions of the truth which a factfinder must resolve at an ensuing trial").

[59] *See also Maldonado-Denis v. Castillo Rodriguez*, 23 F.3d 576, 583 (1st Cir. 1994) ("tenuous assertions strung together by strands of speculation and surmise" cannot defeat summary judgment).

infringing (violating) the patent ends the litigation by paying the holder of the patent to settle[.]"[60]

The Agreement takes this traditional form: it provides that Par, the accused infringer, will pay royalties to Sucampo, the patent holder, in exchange for a license to enter the market before expiration of Sucampo's patents.[61] Despite the undisputed direction of this flow of money, Plaintiffs claim that the Agreement contains a "reverse" payment. They advance three separate (and sometimes conflicting) theories of such a payment. *First*, they allege that the Agreement's declining royalty structure, whereby Par's royalty rate would be reduced upon Sucampo and Takeda's launch of a competing AG, resulted in a "de facto no-AG agreement," because it disincentivized Sucampo and Takeda from launching a competing AG, resulting in higher generic prices and greater profits to Par from its AG product sales.[62] *Second*, Plaintiffs now claim that the Agreement's 50% royalty rate itself—irrespective of any decline—created a functional no-AG agreement because the royalty rate was so generous to Sucampo that it disincentivized Sucampo and Takeda from launching a competing AG.[63] *Third*, presumably in the alternative, Plaintiffs assert that the Agreement's 50% royalty rate was "far-below market rate," allowing Par to keep more profits from its AG sales than is typical under AG licenses, which resulted in a "payment" to Par.[64] The Court should reject each of these theories as a matter of law.

A. Par's 50% Royalty Rate On Amitiza AG Sales Does Not Decline

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[60] DPP's Omnibus Opp'n to Defs.' Mot. to Dismiss, ECF No. 49, at 5.
[61] SOF ¶¶ 22-24, 83-92.
[62] *See* DPP Compl., ECF No. 28, ¶¶ 229-31. A "no-AG" agreement provides—either tacitly or expressly—that the brand manufacturer will not market an AG for a certain period of time, often during a first-filer's 180-day exclusivity period. *See Nexium*, 842 F.3d at 42, 56; *cf. Somaxon Pharm., Inc. v. Actavis Elizabeth LLC*, No. CV 10-1100-RGA-MPT, 2020 WL 1903171, at *3 (D. Del. Apr. 9, 2020). A no-AG agreement may be subject to rule-of-reason scrutiny where it "'[could] represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that [could not] be adequately justified." *Somaxon*, 2020 WL 3470471, at *4 (quoting *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 409 (3d Cir. 2015)) (alterations supplied); *see also id.* at *3-4, nn.11, 14 ("The Court can find no authority that has found no-AG provisions to be *per se* illegal" as such would "conflict with [*Actavis*]'s explicit rejection of presumptive illegality[.]").
[63] *See* Ex. 94B (Ruhm Rebuttal) ¶¶ 44-47; *see also* EPP Compl., ECF No. 1, ¶ 162; Retailer Compl., ECF No. 1, ¶ 133; CVS Compl., ECF No. 1, ¶ 131.
[64] *See* DPP Compl., ECF No. 28, ¶ 219.

Plaintiffs' first theory of a reverse payment—that the Settlement Agreement's declining royalty structure created a *de facto* no-AG agreement—was alleged in Plaintiffs' Complaints.[65] Plaintiffs alleged that Par would pay a declining royalty on its gross profits from the sales of generic Amitiza based on the number of other generic entrants; specifically, Par would pay (1) 50% as the only generic on the market, (2) 15% with one other generic on the market including an AG, and (3) no royalty with two or more additional generics, including an AG.[66] In opposing Takeda's motion to dismiss, Plaintiffs claimed that "[t]his royalty structure applies whether or not Par launched a Sucampo-supplied AG or its own ANDA product."[67]

This theory is based entirely on a misreading of the Agreement. The Agreement's unambiguous terms state that [redacted] *i.e.*, a "Generic Equivalent," as expressly defined in the Agreement as "a pharmaceutical product that has received FDA approval. . . pursuant to an ANDA").[68] Par, having failed to receive FDA approval to market its ANDA product when it was otherwise licensed under the Agreement, instead exercised its option to market an AG.[69] Because the Agreement's clear terms provide that [redacted], a declining royalty rate structure could not have disincentivized Sucampo and Takeda from launching a competing AG. Takeda is, accordingly, entitled to summary judgment as a matter of law on Plaintiffs' first "declining royalty" reverse-payment theory.

The Agreement is governed by Delaware law,[70] which follows the "'objective' theory of contracts, *i.e.*, a contract's construction should be that which would be understood by an objective,

[65] *See* DPP Compl., ECF No. 28, ¶¶ 228-31; *see also* EPP Compl. ECF No. 1, ¶¶ 156-59; Retailer Compl., ECF No. 1, ¶¶ 126-30; CVS Compl., ECF No. 1, ¶¶ 124-128.
[66] DPP Compl., ECF No. 28, ¶ 212.
[67] DPP Omnibus Opp'n to Defs.' Mot. to Dismiss, ECF No. 49, at 18.
[68] SOF ¶ 24.
[69] SOF ¶ 26-28.
[70] SOF ¶ 24; Ex. 13 (2014 Par Settlement) § 6.3.

reasonable third party." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010).[71] This means that "contracts should be construed according to their plain meaning, . . . not according to forced and refined interpretations which are intelligible only to lawyers[,]" and courts are "not able to consider parol evidence where the language of the contract is clear. If a contract is unambiguous, [courts] must give the language its ordinary meaning." *Pharm. Prod. Dev., Inc. v. TVM Life Sci. Ventures VI, L.P.*, C.A. No. 5688-VCS, 2011 WL 549163, at *2, 4 n.24 (Del. Ch. Feb. 16, 2011) (quoting 17A Am. Jur. 2d Contracts § 396).[72] "[W]hether a contract is ambiguous is a question for the court to resolve as a matter of law" on summary judgment and contract terms are "not rendered ambiguous simply because the parties in litigation differ concerning their meaning, nor because the parties simply do not agree upon [their] proper construction." *Comet Sys., Inc. S'holders' Agent v. MIVA, Inc.*, 980 A.2d 1024, 1030 (Del. Ch. 2008) (internal citations and quotations omitted).[73]

The Agreement's royalty rate structure is unambiguous and provides that a [redacted] Section 3.13 of the Agreement addresses "Royalty Payments and Reporting."[74] Subsection 3.13(a) provides that [redacted]

[71] *See also Bathla v. 913 Mkt., LLC*, 200 A.3d 754, 759-60 (Del. 2018) (courts must "interpret clear and unambiguous terms according to their ordinary meaning"); *Daystar Const. Mgmt., Inc. v. Mitchell*, C.A. No. 04C-05-175-JRS, 2006 WL 2053649, at *9 (Del. Super. Ct. July 12, 2006) ("if the terms of the contract are facially clear, the parties must be held to those terms. It would violate the basic principles of contract construction to allow any other result.") (citing *Dunlap v. State Farm Fire & Cas. Co.*, 878 A.2d 434, 442 (Del. 2005)).

[72] *See also Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997) (extrinsic evidence generally not admissible unless court finds contract's meaning ambiguous).

[73] *See also Sunline Com. Carriers, Inc. v. CITGO Petroleum Corp.*, 206 A.3d 836, 847 n.68 (Del. 2019) (court "cannot find an ambiguous contract unambiguous because each party interprets the contract differently to find it unambiguous."); *GB Bioscis. Corp. v. Ishihara Sangyo Kaisha, Ltd.*, 270 F. Supp. 2d 476, 481 (D. Del. 2003) ("[D]isputes involving the interpretation of unambiguous contracts are resolvable as a matter of law"); *JFE Steel Corp. v. ICI Ams., Inc.*, 797 F. Supp. 2d 452, 469 (D. Del. 2011) ("when two sophisticated parties bargain at arm's length and enter into a contract, the presumption is even stronger that the contract's language should guide the Court's interpretation."); *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 140 (3d Cir. 2019) ("Delaware law holds sophisticated parties . . . to the bargain they actually struck, rather than the one in hindsight they realize they should have made.").

[74] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.13.

[redacted]

[redacted][80]

Because Section 3.12 states that [redacted]

[75] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.13(a) (emphasis added).
[76] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 1.1.
[77] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.12.
[78] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.13(b) (emphasis added).
[79] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.13(c) (emphasis added).
[80] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 1.1 (emphasis added).

[redacted], even though the parties could have easily included such a trigger in the Agreement. *See Oxbow Carbon & Mins. Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC*, 202 A.3d 482, 507 (Del. 2019) (An interpreting court "should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it.") (internal citation omitted).[83]

With Par's AG product being subjected to a flat royalty rate, irrespective of Sucampo and Takeda choosing to launch a second AG, Plaintiffs' case falls well beyond the reach of other "de facto" or implicit no-AG agreement cases, such as *Xyrem*, *Intuniv*, and *Zetia*. For example, *In re Revlimid & Thalomid Purchaser Antitrust Litigation* addressed and rejected a theory that a royalty-free license coupled with a volume cap on a generic's sales constituted a de facto no-AG agreement. No. CV 19-7532 (ES) (MAH), 2024 WL 2861865, at *58, 62 (D.N.J. June 6, 2024). In rejecting this theory, the court distinguished, and cabined to their respective facts, each of *Xyrem*, *Intuniv*, and *Zetia*, which the plaintiffs cited in support of their de facto no-AG agreement theory:

- *Xyrem*: plaintiffs alleged (1) brand-manufacturer Jazz agreed not to license its AG through any third-party (as opposed to launching an AG by itself—a right Jazz

[81] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) § 3.12 (emphasis added).
[82] SOF, ¶ 24; Ex. 13 (2014 Par Settlement) §§ 3.13(b)-(c).
[83] *See also Iron Workers Dist. Council of New Eng. Health and Welfare Fund v. Teva Pharm. Indus. Ltd.*, No. CV 23-11131-NMG, 2024 WL 4700248, at *3-4 (D. Mass. Nov. 6, 2024) (dismissing reverse payment claim where documentary evidence rendered claim implausible). While Plaintiffs' declining royalty theory does not apply to Par's AG launch, warranting dismissal, Plaintiffs also have no support for any notion that the declining royalty applicable to Par's ANDA (which Par did not launch) caused Par to delay launching a generic product.

preserved) during generic-manufacturer Hikma's first 180 days of selling the Hikma AG; and (2) Hikma was obligated to pay "increasingly higher percentages of royalties to Jazz as Hikma's market share increased," which undermined Jazz's economic interest in selling its own AG because such a launch would take market share from Hikma and reduce Hikma's royalty percentage owed to Jazz.

- *Intuniv*: plaintiffs alleged (1) brand-manufacturer Shire would receive a 25% royalty during generic-manufacturer Actavis's first 180 days on the market, as long as Actavis was "the only generic producing Intuniv on the market," expressly including that "Actavis's royalty obligations would terminate if Shire launched an AG;" and (2) Shire could not license a third party to market or sell AG product at any time before the end of Actavis's 180 days of exclusivity or another generic entering the market, though Shire preserved the right to launch an AG by itself.

- *Zetia*: the court found "the settlement agreement at issue could plausibly be read as a no-AG agreement because the agreement only reserved the brand manufacturer's ability to sell a branded and not a generic product" which was supported by "other circumstantial evidence" including that "the generic claimed exclusivity on release of its generic product and that the brand manufacturer failed to release an authorized generic throughout the generic's period of exclusivity."[84]

Like in *Revlimid*, there is no evidence here that (1) Sucampo and Takeda promised not to license an Amitiza AG through a third party (which they later did, in settlements with other ANDA filers), (2) the Agreement's terms otherwise limited in any way Sucampo and Takeda's ability to launch a second AG, (3), the percentage rate of Par's royalty on it sales of AG product was keyed in any way to the introduction of a second AG by Sucampo and Takeda; or (4) Par understood its generic would be exclusive, easily distinguishing each of these cases from this one and more closely aligning it with *Revlimid*.

The Settlement Agreement does not support Plaintiffs' declining royalty theory of liability, nor have Plaintiffs adduced evidence that the contract was otherwise a *de facto* No-AG agreement. As such, Plaintiffs' declining royalty theory of a reverse payment fails as a matter of law.

B. Par's 50% Royalty To Sucampo Does Not Result In A Reverse Payment

[84] 2024 WL 2861865, at *63 (distinguishing *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829 (N.D. Cal. 2021); *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639 (D. Mass. 2020); *In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F. Supp. 3d 418 (E.D. Va. 2019)).

Because It Is Allegedly "Too High."

During the course of discovery, Takeda explained that Plaintiffs' first reverse-payment theory is refuted by the Settlement Agreement's unambiguous terms. Plaintiffs then shifted to a new theory—that the Agreement's 50% royalty was sufficiently high (irrespective of any decline in rate) to keep Sucampo and Takeda from launching a second AG because Sucampo would earn more from royalties on sales of Par's AG than by launching a competing AG product.[85] According to Plaintiffs, this disincentive resulted in a reverse payment to Par. This theory appears nowhere in Plaintiffs' complaints and can be dismissed for that reason alone. *See, e.g.*, *In re Intuniv Antitrust Litig.*, No. 16-cv-12653-ADB2021, WL 10362709, at *11 (D. Mass. Mar. 3, 2021) (precluding unpled independent theory of liability).[86] Moreover, Plaintiffs' newly discovered theory for a reverse payment is not actionable as a matter of law.

In *Actavis*, the Supreme Court addressed an "unusual" "kind of settlement agreement [that] is often called a 'reverse payment,'" when the patent holder induces a potential generic infringer to stay off the market. 570 U.S. at 141, 147. To avoid the threat to its patent rights, the patent holder was alleged to have paid the challenger to drop the suit—*i.e.*, "walk[] away with money simply so it will stay away from the patentee's market"—as compared to "traditional examples" where "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim[.]" *Id.* at 152; *see also id.* at 141 (describing a reverse payment wherein the patent holder "pa[id] the alleged infringer, rather than the other way around."); *Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 714 (7th Cir. 2022) ("*Actavis* adds that one kind of

[85] DPP Compl., ECF No. 28, ¶¶ 223-30; Ex. 94B (Ruhm Rebuttal) ¶¶ 44-47.

[86] Plaintiffs' complaints allege (incorrectly) that the 50% royalty was too *low*, not too *high*. DPP Compl. ECF No. 28, ¶ 219; EPP Comp., ECF No. 1, ¶ 162; Retailer Compl., ECF No. 1, ¶ 133; CVS Compl., ECF No. 1, ¶ 131. An "expert may not pursue a theory of classwide antitrust injury that [the] operative complaint has explicitly repudiated." *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 54 (S.D.N.Y. 2020); *cf Victory Dollar Inc. v. Travelers Cas. Ins. Co. of Am.*, No. 2:22-cv-09120-MCS-RAO, 2023 WL 9003012, at *6 (C.D. Cal. Nov. 22, 2023) (declining to allow unpled theories at summary judgment for lack of fair notice).

settlement, in which the patent holder pays the potential entrant to defer entry, could be unlawful").

What Plaintiffs point to here is a "traditional" or "commonplace" settlement where an infringing defendant (Par) facing a serious challenge to its Paragraph IV certification[87] and uncertainty over its ANDA approval,[88] managed to secure an early date-certain to bring a generic version of a patented product—including a potential AG—to market pursuant to a license by offering to pay the patent holder (Sucampo) a 50% royalty.[89] That is "quite different" from a "reverse payment settlement[]," where "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market." *Actavis*, 570 U.S. at 152. Indeed, the Supreme Court confirmed that parties may settle their lawsuits "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 158.[90] The royalty here runs from the patent challenger Par to the patentee Sucampo, and is therefore not a reverse payment but is "squarely protected by *Actavis*." *Abbvie*, 42 F.4th at 715.

The D.C. Circuit recently rejected a similar theory. In *FTC v. Endo Pharms. Inc.*, the FTC challenged a settlement agreement whereby (1) patent holder Endo granted challenger Impax a license to its patents "in exchange for a monetary payment in addition to a percentage of royalties relating to Impax's gross oxymorphone ER profits," and (2) "Impax's obligation to pay royalties

[87] SOF ¶¶ 18-20.
[88] SOF ¶¶ 26-29.
[89] SOF ¶¶ 20, 22-24; *compare Impax Lab'ys., Inc. v. FTC*, 994 F.3d 484, 487 (5th Cir. 2021) ("Normally, when lawsuits settle the defendant pays the plaintiff.").
[90] *See also Abbvie*, 42 F.4th at 715 (affirming dismissal of reverse payment claim, finding "[t]he terms of the settlement require the entrants to pay royalties on the three indications that remain under patent. That makes the E.U. settlement one of the traditional kinds squarely protected by *Actavis*—and if . . . AbbVie has dropped out of the E.U. market, the licensing of a patented product in exchange for royalties is common and lawful."); Philip Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 2045 ("a firm may settle . . . by unilaterally giving [the patent challenger] an unrestricted or restricted license, with or without royalty" and "[t]he simplest situations posing the least risk of competitive harm are those in which a patentee sues a . . . potential rival for infringement, and . . . settles by giving . . . a nonexclusive license to practice the patent in exchange for royalties").

would terminate if Endo took various actions, such as using its own patents to enter the oxymorphone ER market." 82 F.4th 1196, 1201 (D.C. Cir. 2023). The FTC alleged that the agreement "create[ed] an impermissibly anticompetitive exclusive licensing arrangement[.]" *Id.* at 1203. The D.C. Circuit affirmed dismissal.

The court relied on the Patent Act, noting that "certain exercises of patent rights are lawful despite the Sherman Act's dictates[,]" including patent holder's right to assign or license patent rights "for any royalty[,]" because "'[t]here is nothing unlawful in the requirement that a licensee should pay a royalty to compensate the patentee.'" *Id.* (quoting *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926); *United States v. Line Material Co.*, 333 U.S. 287, 315 (1948)).

Addressing *Actavis*, the D.C. Circuit found that the opinion did not "disturb" traditional exchanges of consideration for patent licenses, but instead "acknowledged the accepted understanding that a patent holder's grant of an exclusive license to a potential competitor in exchange for payment of a royalty generally raises ***no issue under the antitrust laws***." *Id.* at 1204-05 (citing *Actavis*, 570 U.S. at 150) (emphasis added).

Plaintiffs' above-market royalty rate theory is no more than a rehash of the FTC's rejected theory in *Endo*. Par's 50% royalty payment obligation is not a reverse payment because the payment does not flow in the reverse direction, and because the Agreement did not give Par exclusivity,[91] it is even less restrictive than the one at issue in *Endo*.

Were Plaintiffs' theory to be credited, virtually all patent settlements would be subject to antitrust scrutiny—a result that cannot be squared with *Actavis*'s teaching that normal settlements are lawful. *See AbbVie*, 42 F.4th at 714; *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22, 2015) ("a reading of *Actavis* that would

[91] SOF ¶¶ 22-24.

compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment would ignore the limiting principles set forth in the decision, and subject virtually any settlement to antitrust scrutiny—a result the Court could not have intended."), *aff'd in part, vacated in part*, 848 F.3d 89 (2d Cir. 2017).[92] The incentives created by the 50% royalty rate cannot support Plaintiffs' claims as a matter of law.

C. Par's 50% Royalty To Sucampo Does Not Result In A Reverse Payment Because It Is Allegedly "Too Low."

In direct contradiction to their second reverse payment theory, Plaintiffs' third theory is that the Agreement's 50% royalty on Sucampo-supplied Amitiza AG is too ***low***, thereby improperly compensating Par and resulting in a reverse payment. Needless to say, Par's royalty rate cannot simultaneously be both too high, as DPPs' expert Ruhm opines,[93] and too low, as Retailers' proposed expert Leffler opines.[94] Either way, a royalty alone—regardless of rate—is not actionable as a matter of law.

When settling patent litigation and granting a generic company a license, a brand company is not required to extract any royalty at all, which means extracting one that is claimed to be "below market" cannot constitute a reverse payment under *Actavis*.[95] Indeed, the FTC's *Actavis* briefs illustrate this in stark relief: an agreement "on a compromise date of generic entry, ***with or without***

[92] *See also Revlimid*, 2024 WL 2861865, at *64 (dismissing allegations that license terms disincentivized brand company from launching AG, reasoning that "if an allegation that an agreement merely disincentivized a brand manufacturer from launching its own authorized generic sufficed to plead a reverse payment, countless settlement terms could be characterized as disincentivizing an authorized generic"); *cf. Watson Lab'ys, Inc. v. Forest Lab'ys Inc.*, 101 F.4th 223, 238 (2d Cir. 2024) ("An overly restrictive interpretation of *Actavis* would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.") (internal citation and quotation omitted).

[93] *See* Ex. 94B (Ruhm Rebuttal) ¶¶ 44-47; *but see* DPP Compl., ECF No. 28, ¶ 219 (royalty [redacted]).

[94] DPP Compl., ECF No. 28, ¶ 219; Ex. 84B (Leffler Rebuttal) ¶¶ 67-71.

[95] Plaintiffs expert Leffler claims that, based on the "industry standard," Sucampo and Takeda should have demanded 90% of Par's generic Amitiza profits for the use of the Amitiza Patents. Ex. 84B (Leffler Rebuttal) ¶¶ 67-71. This 90% figure comes from a 2011 FTC Report studying licensing agreements arising *outside of patent litigation*. Ex. 206 (2011 FTC Report) at 77. This supposed "industry standard" is therefore implausible on its face.

a licensing royalty . . . is an unalloyed good."[96] The Supreme Court agreed, recognizing that no antitrust liability attaches to "commonplace" settlements over disputed patents. *Actavis*, 570 U.S. at 151. Plaintiffs fail to explain why it is actionable for Sucampo and Takeda to do *in part* (license Par to use the Amitiza patents for a royalty prior to the expiration of the patents) what they unquestionably were entitled to do *in full* (license those same patents for no royalty).[97]

As addressed above, *Actavis* was concerned with a different kind of settlement, where "a party with no claim for damages (something that is usually true of [a Hatch-Waxman] defendant) walks away with money simply so it will stay away from the patentee's market." 570 U.S. at 152. There is no logical way for Plaintiffs to cram a settlement under which Sucampo and Takeda paid Par nothing, but Sucampo simply agreed to ***charge*** a royalty for the use of its patents, into *Actavis*'s narrow focus of concern. By recasting the payment of royalties ***by Par*** as a payment ***by Sucampo and Takeda***, Plaintiffs flip *Actavis* on its head in precisely the way courts forbid.

A similar theory was recently rejected by *Revlimid*. As noted above, the plaintiffs alleged that a royalty-free license in conjunction with a volume cap on the generic's sales "functioned as de facto promise by Celgene not to launch its own authorized generic" that "transferred profits Celgene would have made from its authorized generic to Natco and assured Natco that it would be able to enjoy selling its generic lenalidomide at prices much higher than it otherwise would were

[96] Pet'r Reply Br., *FTC v. Actavis, Inc.*, No. 12-416, 2013 WL 1099171, at *8-9, *12 (U.S. Mar. 18, 2013) (emphasis added). Experts have recognized that royalties in general—even a "below market" royalty—are used to gain an ***earlier***, not later, launch date. *See, e.g.*, Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy & Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 14 (2005) ("Any payment provision in the settlement agreement—beyond the expected savings in litigation costs—would affect the compromise entry date in one direction or another: a payment from the alleged infringer to the patent holder, *i.e.*, a royalty, would be made to gain an earlier entry than a compromise on the date alone. A payment of this kind is unremarkable and indisputably within the limits of a patent's exclusionary power."); *accord* Ex. 206 (2011 FTC Report) at 141 n.4 (citing favorably Abbott & Michel, noting that "[p]ursuant to settlement, a generic company may pay a royalty to the brand to gain an earlier entry date than it would get by compromising on the date alone").

[97] Indeed, the Plaintiff experts' confused solution is a ***zero*** percent royalty (*see, e.g.*, Ex. 84A (Leffler Report) ¶ 82)—*i.e.*, one that would definitively be below market under Plaintiffs' own theory that a 50% rate is too low.

it competing with an AG." *Revlimid*, 2024 WL 2861865, at *58.[98] The court dismissed this theory, finding that the volume cap did not amount to a "'payment' that was made in 'reverse,' from Celgene to Natco under *Actavis*." *Id.* at *57. Specifically, and like here, the court noted that "the Insurer Plaintiffs have not alleged that Celgene promised not to produce an AG" and "even if . . . the volume limited license, standing on its own, did somehow disincentivize Celgene from launching its own AG, '*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible,'" but "requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Id.* at *62. Accordingly, the court "decline[d] to expand *Actavis*'s holding," stating instead that:

> if an allegation that an agreement merely disincentivized a brand manufacturer from launching its own authorized generic sufficed to plead a reverse payment, countless settlement terms could be characterized as disincentivizing an authorized generic. In fact, a similar inference could be drawn from a settlement in which a generic manufacturer is permitted to enter the market before patent expiry but also agrees to respect the patents for a period of time and does not receive any corresponding payment—while the generic stays off the market, the patent owner would have no incentive to launch its own authorized generic. Yet, the Supreme Court's analysis in *Actavis* emphasized that such patent "settlements taking [ ] commonplace forms have not been thought [to be] subject to antitrust liability" and that the *Actavis* decision "do[es] not intend to alter that understanding."[99]

Indeed, *any* benefit that a generic manufacturer acquires in settling Hatch-Waxman litigation and negotiating a patent license in the ordinary course (*e.g.*, entry dates, royalties) could, if viewed from an extreme lens, "be characterized as a . . . payment to the would-be entrant."[100] But *Actavis* "rejected the possibility of treating an 'implicit net payment' as equivalent to an actual payment, characterizing the reverse-payment problem as 'something quite different' from"

[98] The *Revlimid* plaintiffs alleged that a below market royalty rate by itself is a reverse payment, but later conceded that a brand company is entitled to charge whatever royalty it wants, including no royalty whatsoever. *Id.* at *56.
[99] *Id.* at *64 (internal citations omitted).
[100] *AbbVie*, 42 F.4th at 716; *see also Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is . . . classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements").

walking away from potential damages.[101] Plaintiffs cannot posit a reverse payment by claiming that Sucampo declined to demand *sufficient* royalty payments from Par.

* * *

Plaintiffs' claims boil down to the notion that the parties should have entered into some other settlement that Plaintiffs believe would have been even better for Amitiza purchasers.[102] Plaintiffs do not explain why or how a rational patent holder in Sucampo's position would have entered into a similar settlement and licensed its patents before expiry—without (or alternatively, with a much higher) royalty. But even if Plaintiffs had evidence to support such theories, it would still not be viable: "*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible." *King Drug*, 791 F.3d at 409.[103]

Plaintiffs' theories presuppose that courts may subject *every* patent settlement to antitrust scrutiny when a plaintiff can hypothesize *any* alternative, more "procompetitive" settlement. That has never been the law: "[t]he mere fact that pricing for the public *could have been lower* under the terms of a particular settlement agreement does not mean that an antitrust violation results when that theoretical optimal result for consumers is not met." *La. Wholesale Drug Co. v. Shire LLC*, 929 F. Supp. 2d 256, 262 (S.D.N.Y. 2013), *aff'd sub nom.*, *In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014), *as corrected* (June 19, 2014). The Sherman Act does not require courts to rewrite settlement agreements at plaintiffs' behest just because "some other approach might yield greater competition." *Verizon Commc'ns v. Law Off. of Curtis v. Trinko, LLP*, 540 U.S. 398, 415-16 (2004). The Court should enter summary judgment in favor of Takeda because

[101] *See AbbVie*, 42 F.4th at 715-16 (finding that "*Actavis* itself considered, and rejected, the argument that an opportunity cost is the same as a reverse-payment settlement").
[102] *See* DPP Compl., ECF No. 28, ¶¶ 335-40; EPP Compl., ECF No. 1, ¶¶ 262-65; Retailer Compl., ECF No. 1, ¶ 204; CVS Compl., ECF No. 1, ¶ 201.
[103] *See also Actos*, 2015 WL 5610752, at *16 ("*Actavis* . . . does not demand that the brand maximize competition.").

Plaintiffs have failed to show any "reverse payment" as required by *Actavis* and its progeny.

II. PLAINTIFFS FAILED TO ADDUCE EVIDENCE OF AN ANTICOMPETITIVE AGREEMENT TO SUPPORT THEIR SECTION ONE CLAIMS

Section 1 "reaches only 'agreements;'" "[i]t does ***not*** reach independent decisions" by market actors. *White v. R.M. Packer Co.*, 635 F.3d 571, 575 (1st Cir. 2011) (emphasis added). Plaintiffs' Section 1 claims therefore require that they prove the existence of an anticompetitive agreement that unreasonably restrained trade. *See id.* (affirming defense summary judgment).[104]

An "agreement," as the term is used in antitrust parlance, requires "'a meeting of the minds' or 'a common scheme'" supported by evidence "both that [one conspirator] communicated its acquiescence or agreement, and that this was sought by the [other conspirator]." *Monsanto*, 465 U.S. at 764 n.9.[105] "Independent decisions [that] . . . 'lead to the same anticompetitive result as an actual agreement among market actors,' are not prohibited by the federal antitrust laws." *Nexium*, 42 F. Supp. 3d at 250 (quoting *White*, 635 F.3d at 575).

An agreement to restrain competition is not lightly inferred. "Antitrust liability is strong medicine," *Euromodas, Inc. v. Zanella*, 368 F.3d 11, 17 (1st Cir. 2004), and mistaking independent decision making for conspiracy would "chill the very [pro-competitive] conduct the antitrust laws are designed to protect." *Matsushita*, 475 U.S. at 594. For patent settlements, ambiguous inferences of implicit agreements that *contradict* the express terms of a written agreement would undermine parties' ability to execute pro-competitive settlements that accelerate competition. *See Actavis*, 570 U.S. at 154 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit.").

The summary judgment framework for antitrust cases accordingly reflects a unique and

[104] *See also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553 (2007).
[105] *See also Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 999 (3d Cir. 1994).

well-developed standard that seeks "to minimize the risk that legal conduct will be chilled or punished" based solely on evidentiary inferences. *White*, 635 F.3d at 577 (citing *Monsanto,* 465 U.S. at 763). Under this framework, the ordinary rule—requiring "inferences . . . drawn from the underlying facts . . . must be viewed in the light most favorable to the [non-moving] party"—does not apply. *See Matsushita*, 475 U.S. at 587-88 (reversing denial of summary judgment). Instead, an antitrust plaintiff "must produce direct or circumstantial evidence that is ***not only consistent with conspiracy***, but '***tends to exclude the possibility of independent action***.'" *White*, 635 F.3d at 577 (quoting *Monsanto*, 465 U.S. at 764) (emphasis supplied).[106] The Supreme Court expanded on this antitrust-specific rule, holding that there is a "limit[ed] . . . range of permissible inferences from ambiguous evidence in a § 1 case," such that "conduct as consistent with permissible competition as with illegal conspiracy does ***not***, standing alone, support an inference of antitrust conspiracy." *Matsushita*, 475 U.S. at 588 (emphasis supplied).[107]

As shown in § I.A *supra*, Plaintiffs have no direct evidence[108] that, given the unambiguous terms of the Agreement, Sucampo and Takeda entered into an anticompetitive no-AG agreement with Par. In fact, DPPs' expert Dr. Ruhm readily admits that [redacted] [109] *Actavis* describes a reverse payment settlement agreement

[106] *See also Euromodas*, 368 F.3d at 19 ("In Sherman Act cases, however, the permissible inferences that can be drawn from ambiguous evidence are quite limited. If the evidence shows conduct that is as consistent with lawful competition as it is with an illicit conspiracy, it cannot be said to support an inference of concerted action."); *N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc*., 883 F.3d 32, 40 (2d Cir. 2018) ("[c]ourts use [the *Monsanto-Matsushita*] framework for assessing conspiracies" under § 1 of the Sherman Act); *White*, 635 F.3d at 577-78, n.5 (collecting cases).
[107] *See also Evergreen Partnering Grp., Inc. v. Pactiv Corp*., 832 F.3d 1, 11 (1st Cir. 2016) (applying *Matsushita* and affirming summary judgment).
[108] "Direct evidence [of an antitrust] conspiracy must be evidence that is ***explicit and requires no inferences*** to establish the proposition or conclusion being asserted" such that it can "establish, ***on its own***, concerted action among the defendants." *Nexium*, 42 F. Supp. 3d at 252 (quoting *In re Baby Food Antitrust Litig*., 166 F.3d 112, 118 (3d Cir. 1999)) (emphasis supplied); *see also Mayor & City Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013) (citing an example of direct evidence as "a recorded phone call in which two competitors agreed to fix prices.").
[109] *See* Ex. 94A (Ruhm Report) ¶ 117, n.224; Ex. 95 (Ruhm Tr.) at 239:15-21, 240:15-21.

as one that "requires" the brand to pay the generic, 570 U.S. at 140-41; here, Plaintiffs' expert concedes that the agreement requires no such payment.

Nor do Plaintiffs have any contemporaneous evidence that any of Sucampo, Takeda, or Par understood they were entering into a no-AG agreement. *See Impax*, 994 F.3d at 496 ("it is a basic antitrust principle that the impact of an agreement on competition is assessed as of the time it was adopted.") (internal citations and quotations omitted).[110] Rather, Par's post-settlement forecasts modeled an AG launch by Sucampo, suggesting that Par believed it would face competition.[111] Plaintiffs lack any indirect or circumstantial evidence that "tends to exclude the possibility" that Sucampo and Takeda's decisions not to launch an AG was arrived at independently. *See White*, 635 F. 3d at 577 (quoting *Monsanto*, 465 U.S. at 764); *see also Twombly*, 550 U.S. at 556 n.4.

Nor can Plaintiffs second guess Sucampo and Takeda's business decision to ultimately not launch a second AG, irrespective of any agreement on the matter with Par.[112] The law is clear that allowing a jury to infer an agreement (even in part) from such evidence runs afoul of *Monsanto* and *Matsushita*. Indeed, courts have found an antitrust plaintiff's burden all the more heavy when supported by circumstantial evidence claiming that, but for a conspiratorial motive, a defendant would have done something different to further its own interests—*e.g.*, negotiated harder, ramped up capacity quicker, or, as claimed here, pursued an AG launch. *See, e.g.*, *Williamson Oil Co. v. Philip Morris USA*, 346 F.3d 1287, 1311-12 (11th Cir. 2003) (declining to "construe[] as evidence of collusion" (i) a defendant's decision to "turn away from the discount market," (ii) "the lack of analysis that preceded the decisions to match each such individual [price] increase," or (iii) "price

[110] *See also Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (refusing to consider post-agreement invalidation of patent because "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into")
[111] SOF, ¶ 32.
[112] SOF, ¶ 31.

increases despite internal analyses that such increases were not advisable"); *In re Citric Acid*, 191 F.3d 1090, 1100-01 (9th Cir. 1999) (affirming defense summary judgment on price fixing claim and rejecting claimed failure to expand production as such "would subject countless strategic business decisions to second-guessing by courts").[113]

A competitor can always do more (especially with the benefit of hindsight), and courts assessing this sort of evidence "have recognized that firms must have broad discretion to make decisions based on their judgments of what is best for them and that ***business judgments should not be second-guessed*** even where the evidence concerning the rationality of the challenged activities might be subject to reasonable dispute." *Citric Acid*, 191 F.3d at 1101 (emphasis added).[114] Plaintiffs "must show more than that a particular action did not ultimately work to [Takeda's] financial advantage," and there can be no inference of an anticompetitive agreement when "a benign explanation for the action [or omission] is equally or more plausible than a collusive explanation." *Williamson Oil*, 346 F.3d at 1310.

Given the plain and unambiguous language of the Agreement, *see* § I.A, supra, Plaintiffs have no evidence—direct or circumstantial—supporting their no-AG agreement theory.[115] And

[113] *See also Twombly*, 550 U.S. at 568-69 (finding defendant exchange carriers' decision to keep to "their old turf" rather than pursue "attractive business opportunit[ies]" failed to suggest an antitrust conspiracy); *Baby Food*, 166 F.3d at 126-27 (finding decisions "not to invest" in certain markets and to cease "competitive counter offers" among the largest baby food makers in the country "is clearly as consistent with normal business conduct as it is with some alleged conspiracy" such that the court was "unwilling to question such business judgment") (internal quotation marks omitted); *Valley Liquors, Inc. v. Renfield Imps., Ltd.*, 822 F.2d 656, 662 (7th Cir. 1987) (affirming summary judgment and finding evidence that a new distributor retained by defendant performed poorly was "at most . . . bad business judgment" that did not justify an inference of collusive price fixing); *In re Delta/Airtran Baggage Fee Antitrust Litig.*, 245 F. Supp. 3d 1343, 1379-80 (N.D. Ga. 2017) (pricing decisions did not implicate "existence of a conspiratorial agreement merely because the wisdom of Defendants' decisions might not be impervious to questioning"); *Cason-Merenda v. Detroit Med. Ctr.*, 862 F. Supp. 2d 603, 641 (E.D. Mich. 2012) (decision, while "sub-optimal from an economic and completive standpoint," was a "business judgment[]" that "courts have cautioned against second-guessing") (internal quotation marks omitted).

[114] *See also H.L. Moore Drug Exch. v. Eli Lilly & Co*., 662 F.2d 935, 941 (2d Cir. 1981) ("[T]he mere fact that a business reason advanced by a defendant . . . is undermined does not, by itself, justify the inference that the conduct was therefore the result of a conspiracy.").

[115] Plaintiffs' failure to produce evidence of an agreement is also fatal to their monopolization claims because the only alleged anticompetitive conduct is that the parties entered into an alleged anticompetitive agreement. *See* EPP Compl.,

anything Plaintiffs could possibly point to as circumstantial evidence of an anticompetitive agreement with Par—*e.g.,* Sucampo and Takeda choosing not to launch a second AG—would "require[] the jury to engage in speculation and conjecture to such a degree as to render its finding a guess or mere possibility." *Williamson Oil*, 346 F.3d at 1302 (internal quotation marks and citation omitted). Absent the existence of an alleged anticompetitive agreement, expert or other testimony purporting to demonstrate that Takeda would have done *something* different—a threshold impossible to define—is insufficient to avoid summary judgment.

III. PLAINTIFFS CANNOT ESTABLISH MARKET OR MONOPOLY POWER

"A failure to show market power is *fatal* to an antitrust claim analyzed under the Rule of Reason." *Am. Tel. & Tel. Co. v. IMR Cap. Corp.*, 888 F. Supp. 221, 253 (D. Mass. 1995). Plaintiffs bear the burden of proving that Takeda possessed either "market power" (for claims under Section 1 and state law analogues)[116] or "monopoly power" (for claims under Section 2 and state law analogues)[117] in the properly defined market in which Amitiza competes. *Lawton v. State Mut. Life Assur. Co. of Am.*, 101 F.3d 218, 223 (1st Cir. 1996). Because Plaintiffs cannot demonstrate—through either direct or indirect evidence[118]—that Takeda possessed market or monopoly power, the Court should grant summary judgment. *See Mylan Pharms. Inc. v. Warner Chilcott Pub. Co.*, 838 F.3d 421, 427 (3d Cir. 2016) (affirming summary judgment for lack of market power).

A. Plaintiffs' Purported Direct Evidence Is Insufficient As A Matter Of Law.

ECF No. 1, ¶¶ 262-65; Retailer Compl., ECF No. 1, ¶ 210; CVS Compl., ECF No. 1, ¶ 210. DPPs have not pursued a similar claim. *See* Order on Motion to Dismiss, C.A. No. 21-11255, ECF No. 41 (D. Mass. Dec. 27, 2020), at 7 n.4.

[116] Market power "is [the defendant's] power to lessen or eliminate competition in the relevant market." *Flovac, Inc. v. Airvac, Inc.*, 817 F.3d 849, 853 (1st Cir. 2016). "[A] patent does not necessarily confer market power." *FTC v. AbbVie, Inc.*, 329 F. Supp. 3d 98, 127 (E.D. Pa. 2018), *aff'd in part, rev'd in part*, 976 F.3d 327 (3d. Cir. 2020) (quoting *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45 (2006)).

[117] Monopoly power is "the power to control prices or exclude competition" within the market. *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). Failure to prove market power is necessarily a failure to demonstrate monopoly power. *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.,* No. 14-md-02503, 2018 WL 563144, at *4 n.5 (D. Mass. Jan. 25, 2018) (citation omitted) (collecting cases).

[118] Market power is proven either by "direct" or by "indirect" evidence. *Coastal Fuels of P.R., Inc. v. Caribbean Petrol. Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996).

For direct evidence, Plaintiffs point to: (1) profit margins for Amitiza prior to generic entry; (2) the decline in the price of Amitiza following generic entry; and (3) Plaintiffs' own reverse payment allegations. None is sufficient to establish market power as a matter of law.

First, Plaintiffs argue that "high gross margins of Amitiza" demonstrate market power.[119] But "inferring market power from gross margins is a dicey proposition, and high gross margins are generally not by themselves sufficient to prove such power."[120] *Garnica v. HomeTeam Pest Def., Inc.*, 230 F. Supp. 3d 1155, 1159 (N.D. Cal. 2017). In markets for products with high fixed costs, such as branded pharmaceuticals, evidence of high margins alone is insufficient. *Intuniv*, 496 F. Supp. 3d at 659 (quoting *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 484 (D. Mass. 2017)). Accordingly, direct evidence of market power requires evidence of both high margins ***and*** restricted output. *Solodyn*, 2018 WL 563144, at *12 ("Absent any evidence of restricted output, [] evidence of high margins is insufficient as a matter of law to demonstrate market power.").[121]

Here, Plaintiffs have shown no evidence of restricted output. Plaintiffs' economic experts Dr. Maestas and Dr. Leffler both admitted that Amitiza output did not increase when Par entered with generic Amitiza in 2021, as would be necessary to show that output was restricted prior to that entry.[122] And after Par's generic entry, it quickly captured a larger share of Amitiza sales than Takeda.[123] Consequently, if Plaintiffs cannot establish market power through output restriction prior to Par's entry, they cannot establish market power after Par had entered the market.

Plaintiffs' second category of direct evidence—Amitiza price declines after generic

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[119] SOF ¶ 40.
[120] *See also Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1412 (7th Cir. 1995) ("[I]t is always treacherous to try to infer monopoly power from a high rate of return.").
[121] *See also Sterling Merch., Inc. v. Nestle, S.A.*, 724 F.Supp.2d 245, 268 (D.P.R. 2010) (explaining that "market power exists only when competitors lack capacity to increase short run output, allowing for the monopolist to unilaterally restrict output in order to charge higher prices").
[122] SOF ¶¶ 41-42; Ex. 38 (Maestas Tr.) 127:19-22 ("Q. The output did not go up when Par entered with a generic Amitiza product; correct? A. Correct.").
[123] SOF ¶ 64.

entry[124]—fares no better. The fact that prices fell after generic entry does not establish that Takeda had market power. If that were the case, virtually all brand pharmaceutical companies would be deemed monopolists.[125] To avoid this absurd result, courts have found that price declines alone are insufficient direct evidence of market power.[126] Indeed, "[w]ithout evidence that sheds light on material factors such as [the alleged monopolist's] price *relative to its total costs (marginal and fixed)* and *whether output was restricted*, monopoly power cannot be found as a matter of law."[127] Here, in addition to failing to show output restriction, Plaintiffs' experts failed to assess Amitiza's price relative to *total costs*,[128] limiting their analysis to marginal costs.[129] Thus, Plaintiffs are unable to demonstrate market power through mere evidence of price declines after generic entry.

Third, Plaintiffs argue that alleged "large and unjustified payments for delays of generic competition" are direct evidence of market power.[130] But Plaintiffs cannot rely on their own allegations as evidence at summary judgment. *Solodyn*, 2018 WL 563144, at *5 (holding that, although the alleged existence of a reverse payment is sufficient at the motion-to-dismiss stage, it is not evidence of market power at the summary judgment stage). Further, the undisputed facts in this case show the flow of payments went from Par (the generic) to Sucampo (the brand); as a result, there is no "reverse payment." *See* § I.B, *supra*. Therefore, Plaintiffs are unable to demonstrate market power through their own allegations of reverse payments.

B. Plaintiffs' Purported Indirect Evidence Is Insufficient As A Matter Of Law.

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[124] SOF ¶ 44.
[125] *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) ("Plaintiffs' approach, if applied beyond this case, would render most brand name pharmaceutical companies as per se monopolists prior to generic entry . . . . Clearly, there must be more proof than just a showing that a brand name drug costs more than a generic equivalent.").
[126] *Id.* at 682.
[127] *Mylan Pharms., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3284, 2015 WL 1736957, at *7 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016) (quoting *Remeron*, 367 F.Supp.2d at 681 n.10) (emphasis added).
[128] As explained more fully in Takeda's motion to exclude the testimony of Dr. Maestas, her analysis did not take into account *total costs*, and thus should be disregarded as unreliable.
[129] SOF ¶¶ 45-46.
[130] SOF ¶ 47.

To establish market power using indirect evidence, Plaintiffs must "show[] that the defendant has a *dominant share* in a *well-defined relevant market* and that there are significant barriers to entry in that market and that existing competitors lack the capacity to increase their output in the short run." *Coastal Fuels*, 79 F.3d at 197 (emphasis added). Here, a properly defined market includes other chronic constipation drugs ("CCDs"), and undisputed facts show Takeda's market share was well below the "dominant share" needed to demonstrate market power.[131] And Plaintiffs have failed to show that existing CCD competitors lacked the capacity to increase their output. Thus, Plaintiffs have failed to establish market power through indirect evidence.

1. Plaintiffs Cannot Prove That The Relevant Market Is Limited To Amitiza And Its Generic Equivalent.

Plaintiffs bear the burden of presenting evidence to define the relevant market.[132] The boundaries of a product market extend to a product and its reasonable substitutes, and "are determined by the reasonable interchangeability of use or the cross-elasticity of demand . . . between the product itself and substitutes for it."[133] A relevant market "is composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered."[134] "The market is established by examining both the substitutes that a consumer might employ and the extent to which consumers will change their consumption of one product in response to a price change in another, *i.e.*, the cross-elasticity of demand."[135]

Plaintiffs incorrectly assert that the market consists of only brand Amitiza and its generic

[131] *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 37 n.7 (1984) (O'Connor, J., concurring) ("[A] patent holder has no market power in any relevant sense if there are close substitutes for the patented product."). For purposes of this motion, Takeda relies only on "second-line" chronic constipation drugs as close substitutes, including Linzess, Relistor, Symproic, Zelnorm, Motegrity, Movantik, and Trulance. There is evidence of additional substitutes in this market, and Takeda reserves the right to refer to these competitors in later proceedings.
[132] *See Coastal Fuels*, 79 F.3d at 197.
[133] *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).
[134] *E.I. du Pont de Nemours & Co.*, 351 U.S. at 404.
[135] *Flovac*, 817 F.3d at 854 (quoting *Eastman Kodak Co. v. Image Tech. Servs, Inc.*, 504 U.S. 451, 469 (1992)) (quotation marks omitted).

substitutes. But products need not be perfect substitutes in order to be considered "reasonably interchangeable,"[136] and markets limited to a single product are found only in "rare circumstances."[137] Here, the undisputed facts show that Amitiza is just one of several treatments for chronic constipation, and that it is reasonably interchangeable with other CCDs.[138] Takeda's expert Dr. Jena opined that [redacted].[139] Unlike Dr. Jena, Drs. Maestas and Leffler are not physicians and thus do not dispute therapeutic interchangeability.[140] Although Plaintiffs' physician expert (Dr. Warfield) supports their narrow view of the market, he admitted that [redacted][141]

Contemporaneous evidence from Takeda and other companies in the CCD market further demonstrates that Amitiza competes with other CCDs, and did so throughout the relevant time period.[142] [redacted] 's market definition in October 2014 included Linzess, Relistor, and Movantik; consequently, [redacted][145] Indeed, Dr. Maestas admits

[136] *See, e.g., Mylan.*, 838 F.3d at 436.
[137] *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992); *see also Mylan*, 2015 WL 1736957, at *10 ("Interchangeability is defined by rough equivalence, not perfect correspondence."); *Kaiser Found. v. Abbott Lab'ys.*, No. CV 02-2443-JFW (FMOx), 2009 WL 3877513, at *9 (C.D. Cal. Oct. 8, 2009) ("[C]ourts have consistently held that a brand name product cannot define a relevant market.").
[138] Clinical guidelines from the American Gastroenterological Association and the American College of Gastroenterology indicate that Amitiza is one of several options available for its three FDA-approved indications. SOF ¶ 58.
[139] SOF ¶ 57.
[140] SOF ¶¶ 48-49.
[141] SOF ¶ 50.
[142] *See Coastal Fuels*, 79 F.3d at 197 ("If the sales of other producers substantially constrain the price-increasing ability of the hypothetical cartel, these others are part of the market.").
[143] SOF ¶ 33.
[144] SOF ¶ 34.
[145] SOF ¶ 35.

that [redacted],[146] and Dr. Leffler concedes that this practice is evidence of price competition.[147]

Documents from competing pharmaceutical companies likewise show that their CCDs competed with Amitiza. [redacted][149] This contemporaneous, undisputed evidence establishes that Amitiza and other CCDs are reasonably interchangeable.

In addition to reasonable interchangeability, courts also consider "the cross-elasticity of demand."[150] "The focus in this demand analysis is on the perspective of the consumers. . . ."[151] *Solodyn*, 2018 WL 563144, at *5 (quoting *Flovac*, 817 F.3d at 855) (marks omitted). Accordingly, courts can consider end-patient prices in assessing competition,[152] and Plaintiffs' own experts do not dispute the role of patient prices in driving demand for CCDs.[153] An analysis of cross-elasticities of demand shows a relevant market broader than Amitiza and its generic equivalents.[154]

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[146] SOF ¶ 51.
[147] SOF ¶ 52.
[148] SOF ¶ 36.
[149] SOF ¶ 37.
[150] *Flovac*, 817 F.3d at 854.
[151] As explained more fully in Takeda's motion to exclude the testimony of Dr. Maestas, her analysis of cross-elasticity is unreliable because it does not take the actual (net) prices paid by patients and third-party payors (like health plans) into account. *See State of N.Y. v. Kraft Gen. Foods, Inc.*, 926 F. Supp. 321, 346 (S.D.N.Y. 1995) (criticizing plaintiff's expert for using retail price data "without taking into account the effect of manufacturer coupons on the average retail prices" of the product). Such flawed indirect evidence is insufficient to prove market power.
[152] *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 572 (6th Cir. 2014) (rejecting argument that the FTC erred by assessing substitutability from the perspective of end patients); *see also Mylan*, 838 F.3d at 437 ("[W]e view the customer response to the various changes in Doryx's prescription couponing scheme . . . as a strong indication of the existence of cross-elasticity"); *Kraft*, 926 F. Supp. at 346 (criticizing plaintiff's expert for using retail price data "without taking into account the effect of manufacturer coupons on the average retail prices" of the product).
[153] *See* SOF ¶¶ 55-56.
[154] *See* SOF ¶ 58. As explained more fully in Takeda's motion to exclude the testimony of Dr. Maestas, Dr. Maestas relies on the Hypothetical Monopolist Test ("HMT") to find that the indirect evidence suggests market power by Takeda. "Because of the uniqueness of the pharmaceutical industry, the hypothetical monopolist test is not necessarily the appropriate means by which to demonstrate cross-elasticity of demand." *Intuniv*, 496 F. Supp.3d at 664; *see also*

Plaintiffs' experts do not dispute that Amitiza demonstrated cross-elasticities with other CCDs.[155]

Plaintiffs have themselves admitted that Amitiza competed with other CCDs in the market. CVS testified that [redacted].[156] Likewise, Walgreen testified that [redacted][157] These admissions further show that the relevant market was broader than only Amitiza and its generic equivalent.

C. Takeda's Market Share In A Properly Defined Market Is Insufficient To Establish Market Power.

Takeda's market share falls well short of "a dominant share in a well-defined relevant market."[158] Courts generally have required a market share of greater than 30% for market power and at least 50% for monopoly power. *See, e.g., Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1439 (9th Cir. 1995) ("a market share of 30 percent is presumptively insufficient to establish the power to control price"); *Broadway Delivery Corp. v. United Parcel Serv. Of Am., Inc.*, 651 F.2d 122, 129 (2d Cir. 1981) ("a market share below 50% is rarely evidence of monopoly power").[159] Here, when competing CCDs are included in the relevant market, Takeda's share is less than 30% in the relevant time period. [redacted].[160] [redacted]

AbbVie, 329 F. Supp. 3d at 130 (criticizing use of HMT test in reverse payment cases as it "would result in a market limited to a brand-name drug and its AB-rated generic in almost every instance").

[155] *See, e.g.*, SOF ¶¶ 53-54.

[156] SOF ¶ 38.

[157] SOF ¶ 39.

[158] *Coastal Fuels*, 79 F.3d at 197.

[159] *See also Grappone, Inc. v. Subaru of New Eng., Inc.*, 858 F.2d 792, 797 (1st Cir. 1988) (if 30% share "did *not* show market power," smaller figures could not show the contrary) (emphasis in original); *PSI Repair Servs., Inc. v. Honeywell, Inc.*, 104 F.3d 811, 818 (6th Cir. 1997) (30% market share "standing alone, provides an insufficient basis from which to infer market power"); *Mylan*, 2015 WL 1736957, at *11 ("Defendants' share of this market—some 18%—is not predominant.") (citation omitted).

[160] SOF ¶¶ 62-63.

[redacted].[161] Amitiza can hardly be said to have market power when its market share is less than half that of Linzess. Plaintiffs are unable to demonstrate market power through indirect evidence.

In sum, because Plaintiffs cannot establish that Takeda had either market or monopoly power in the relevant market, they cannot establish a violation of the antitrust laws under the rule of reason, even if they were to prevail on all other aspects of their claims. Accordingly, the Court should grant summary judgment to Takeda on all of Plaintiffs' antitrust claims.

IV. THE AGREEMENT DID NOT CAUSE DELAY/INJURY/DAMAGES

A. Plaintiffs Failed To Establish That Par Would Have Been Able To Lawfully Launch Its ANDA Product Even If It Had Won The Par Patent Litigation

"To establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury—that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful.'"[162] In a generic delay case like this one, where plaintiff alleges that its injury was caused by the settlement of patent litigation, Plaintiffs must show that the harm (*i.e.*, the delay) they purportedly suffered from was "caused by the settlement they are complaining about."[163] Plaintiffs must show that generic launch would not have been blocked by patents covering Amitiza.[164] As the Third Circuit explained in *Wellbutrin*, "if the

[161] SOF ¶¶ 60-61.

[162] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164 (3d Cir. 2017) (quoting *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 233 (3d Cir. 2013) (alteration in original) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977))).

[163] *In re Wellbutrin*, 868 F.3d at 164-65; s*ee also Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 334 (1990) (injury "will not qualify as 'antitrust injury' unless it is attributable to an anti-competitive aspect of the practice under scrutiny"). Plaintiffs bear the burden of proving that the alleged anticompetitive agreement was the "material cause" of alleged "overcharges" incurred by Plaintiffs due to delayed generic entry. *Solodyn*, 2018 WL 563144, at *13 ("In an antitrust case, plaintiffs must demonstrate that the antitrust violation was a 'material cause' of their injury.") (quoting *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1103 (1st Cir. 1994)).

[164] *Wellbutrin*, 868 F.3d at 165; s*ee also Nexium*, 842 F.3d at 62-63 ("[T]he argument that [the generic manufacturer] would have incurred the risk of launching at risk or that [it] would have won its . . . suit against [the patent holder] depends on the theory that . . . [the] patents were invalid or not infringed by a generic version."); Phillip E. Areeda & Herbert Hovenkamp, *Fundamentals of Antitrust Law* § 3.04[B] (rev. 4th ed. Supp. 2021-2) ("[A] plaintiff cannot be

launch were stopped because it was illegal, then the [plaintiffs'] injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch."[165]

Plaintiffs concede that patent clearance, *i.e.*, "removal of any remaining patent barriers," is a prerequisite for Par entering the market with its ANDA product earlier than the licensed entry date under the Agreement.[166] Plaintiffs incorrectly assume, however, that Par prevailing in the Par Patent Litigation—in which Sucampo asserted seven patents against Par's ANDA products—would have cleared all patent barriers to Par's launch.[167] But the evidence shows that Par would have had to clear two ***additional*** Orange Book patents via ***a second*** Hatch-Waxman litigation before Par could launch its own generic Amitiza product. Because Plaintiffs fail to take these two other blocking patents into account, they fail to show that their injuries were caused by the Settlement, and lack standing to pursue their antitrust claims.

It is "beyond fair dispute" that a legislative bar can break the chain of causation in an antitrust case.[168] Patents confer exclusionary rights that legally bar a generic's launch.[169] "[I]t only takes one valid, infringed patent to render all the rest . . . irrelevant for purposes of cause-in-fact analysis" because "[i]f a drug is not able to launch because launching would infringe even a single patent, then the 'injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch.'"[170] Thus, Plaintiffs must show how a generic would

injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").

[165] *Wellbutrin*, 868 F.3d at 165.

[166] SOF ¶ 103; s*ee also* Ex. 75A (Clark Report), ¶ 150.

[167] SOF § IX.E (¶¶ 96-115).

[168] *Id.*; *RSA Media*, 260 F.3d at 15; *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389 (PGS/JBD), 2024 WL 2866654, at *26 (D.N.J. June 6, 2024).

[169] *Nexium*, 842 F.3d at 63-64 (affirming jury verdict for antitrust defendant in part because plaintiff did not present "evidence that the brand-name's patents would have been declared invalid or that an at-risk launch would not have infringed the patents") (alteration in original) (quoting *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 767 (E.D. Pa. 2015)).

[170] *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 844 (N.D. Ill. 2020), *aff'd*, 42 F.4th 709 (7th Cir. 2022) (quoting *In re Wellbutrin*, 868 F.3d at 165).

have full patent clearance earlier than the challenged generic launch date.[171] Absent this showing, Plaintiffs have "failed to show that their injuries were caused by the overall settlement" and "thus do not have antitrust standing."[172] It is not required "that patent litigation be commenced or that an ANDA be filed for a court to determine whether the patent breaks the chain of causation."[173]

In the Par Patent Litigation, Sucampo asserted six Orange Book patents, then amended the complaint to add a seventh.[174] Later, during expert discovery, Sucampo obtained two additional patents covering Amitiza.[175] On June 10, 2014, Sucampo was awarded U.S. Patent No. 8,748,481 ("the '481 Patent"), directed to methods of using compounds (including lubiprostone) to treat chronic constipation.[176] That Patent expires in September 2025.[177] On July 15, 2014, Sucampo was granted U.S. Patent No. 8,779,187 ("the '187 Patent"), directed to soft gelatin capsule formulations of compounds including lubiprostone.[178] That expires in January 2027.[179]

Par knew that Sucampo continued to prosecute patents covering Amitiza. Par testified that [redacted]

[171] *Wellbutrin*, 868 F.3d at 166-70.
[172] *Id.* at 169; *see also Humira*, 465 F. Supp. 3d at 844-46 (dismissing federal antitrust claims for lack of antitrust injury where plaintiffs failed to allege that all of the brand's patents were invalid or not infringed); *Revlimid*, 2024 WL 2861865, at *84, 109-12 (granting motion to dismiss because plaintiffs failed to "allege that ***all*** of [defendant's] patents were invalid and/or were not infringed" by generics and a single valid, infringed patent could "preclude [the] generics from entering the market").
[173] *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App'x 399, 404 (3d Cir. 2021).
[174] SOF ¶¶ 68-69; s*ee also* Ex. 12 (Par Patent Litig. Compl.) at TAKAMI1210217; Ex. 19 (Par Patent Litig., Am. Compl.) at TAKAMI1210490-92.
[175] SOF § IX.B (¶¶ 71-82). Both of these new Sucampo patents were subsequently added to the Orange Book for the 8mcg and 24mcg strengths of AMITIZA. SOF ¶¶ 74, 81; *see also* Ex. 119 (FDA Orange Book (34th ed. cumulative suppl.) at A-13; Ex. 120 (FDA Orange Book (34th ed. cumulative suppl.) at A-16.
[176] SOF ¶¶ 71-73; s*ee also* Ex. 113 ('481 Patent) at [45], [54], [73], [57].
[177] SOF ¶ 75; s*ee also* Ex. 113 ('481 Patent) at [22]; Ex. 122 (FDA Orange Book (35th ed. 2015) at TAKAMI1277178, TAKAMI1277180. The '481 Patent is not related to the seven Sucampo patents that Par asserted in the Par Patent Litigation; it has a different specification and unique claims. SOF ¶¶ 72-73; *see also* Ex. 113 ('481 Patent) at [60], 22:62-24:37. For example, the '481 Patent's claims are directed to methods of treatment for the "long term treatment of chronic constipation in a human subject" at a dosage of 6-48 mcg per day for at least four weeks, wherein the treatment induces substantially no serum electrolyte shifting during the term of treatment, and wherein the treatment improves quality of life of the subject. SOF ¶ 73; *see also* Ex. 113 ('481 Patent) at 22:62-24:37.
[178] SOF ¶¶ 76-80; *see also* Ex. 114 ('187 Patent) at [45], [54], [73], 13:58-15:10.
[179] SOF ¶ 82; *see also* Ex. 113 ('481 Patent) at [63]; Ex. 122 (FDA Orange Book (35th ed. 2015)) at TAKAMI1277178, TAKAMI1277180.

[redacted].[180] Par's 30(b)(6) witness, Gina Gencarelli—a Hatch-Waxman patent litigator who represented Par as outside counsel during the Par Patent Litigation and later joined Par's in-house legal team prior to the settlement—testified that [redacted][181]

Takeda's expert, Mr. Jonathan Singer, an experienced Hatch-Waxman trial attorney, opined that, [redacted][182] Similarly Takeda's expert, Dr. Josephine Liu, an experienced Hatch-Waxman litigator with extensive in-house experience managing Hatch-Waxman litigation, opined that [redacted][183] Plaintiffs have proffered no expert opinions (either from a brand or generic perspective) contradicting these conclusions.

Accordingly, winning the Par Patent Litigation would not have provided Par full patent clearance, as the Agreement did. The Agreement states that [redacted]

[180] SOF ¶ 85; *see also* Ex. 79 (Gencarelli Tr.) at 102:2-13.
[181] SOF ¶¶ 84-87 (emphasis added); *see also* Ex. 116 (Apr. 4, 2024 Correspondence) 1-2; Ex. 79 (Gencarelli Tr.) at 85:10-86:23, 102:2-13, 102:15-19, 117:5-14.
[182] SOF ¶ 99 (emphasis added); *see also* Ex. 97 (Singer Rep.) ¶ 131. Likewise, Mr. Singer also concluded because the '481 and '187 Patents "were not part of the Par Hatch-Waxman Litigation, [] Sucampo could have filed another patent infringement lawsuit as to those patents." SOF ¶ 98; *see also* Ex. 97 (Singer Rep.), ¶ 131.
[183] SOF ¶ 100 (emphasis added); *see also* Ex. 86 (Liu Report) ¶ 98.

[redacted].[184] When asked about this statement, Par testified that the [redacted] [185] Thus, even if it had won the Par Patent Litigation, Par would still need to ***subsequently*** defeat at least Sucampo's newest Orange Book patents to launch risk-free (or wait until patent expiry in 2027).[186] Defeating these patents would require litigating the unique claims of the '481 and '187 Patents, which were not part of the Par Patent Litigation.[187] Accordingly, Par negotiated a license to the seven Sucampo patents that were asserted in the litigation (§ 3.1) and a broad covenant-not-to-sue that covered the '481 and '187 Patents (§ 3.2).[188]

Accordingly, even assuming (for purposes of this Motion only) that Par was more likely than not to prevail in the Par Patent Litigation, Par would still have needed a "final resolution" and "certainty" as to at least these newly-issued, unexpired Orange Book patents.[189] While Plaintiffs' expert, Dr. Michael Davitz, [redacted].[190] Plaintiffs' other industry and economic experts (Mr. Clark, Dr. Conti, Dr. Leffler, and

[184] SOF ¶ 89; *see also* Ex. 13 (2014 Par Settlement) at TAKAMI0000064.
[185] SOF ¶ 87 (emphasis added); *see also* Ex. 79 (Gencarelli Tr.) 117:5-14.
[186] *See generally* 21 C.F.R. 314.94(a)(12)(viii)(C)(1)(ii) (requiring ANDA applicant to submit an appropriate patent certification where a new patent is issued by the U.S. Patent Office).
[187] SOF ¶¶ 68-69; SOF ¶¶ 78-80.
[188] SOF ¶¶ 90-91; *see also* Ex. 13 (2014 Par Settlement) §§ 3.1, 3.2. Dr. Liu concluded that an "experienced in-house counsel in Par's position at the time of settlement would have been aware that a settlement agreement that covered Sucampo's unasserted patents would substantially reduce the risk of follow-on patent litigation that could further delay Par's launch and/or make it liable for substantial patent damages." SOF ¶ 101; *see also* Ex. 86 (Liu Report) ¶ 99.
[189] SOF ¶¶ 85, 87.
[190] SOF ¶ 96; *see also* Ex. 78A (Davitz Rep.) ¶ 6. [redacted] SOF ¶ 98; *see also* Ex. 78A (Davitz Rep.) ¶¶ 647, 651-54. [redacted]. SOF ¶¶ 99-100; *see also* Ex. 97 (Singer Rep.) ¶ 131; Ex. 86

Dr. Ruhm) [redacted].[191] Because Dr. Davitz's analysis omitted the two newer patents not at issue in the Par Patent Litigation, Plaintiffs' experts have not addressed the obvious risk of "future litigation against Par" referenced in the Settlement Agreement. Plaintiffs' failure of proof is fatal. By ignoring the existence of these patents in each of their damages Scenarios 1-3, Plaintiffs failed to ascribe value to those patents, ignored Par's substantial risk of follow-on litigation, and treated Par's covenant-not-to-sue as meaningless boilerplate that Sucampo would have given away *gratis*.[192] There is no logic or evidence to justify any of those implicit assumptions. In sum, Plaintiffs cannot show that their alleged injury was caused by the Agreement, because without that Settlement Agreement Par's entry would have been foreclosed by valid patents prohibiting Par's launch until 2027.[193] Accordingly, Plaintiffs do not have antitrust standing.[194]

B. Par Lacked Regulatory Approval To Sell Generic Amitiza Until June 2022 Without Regard To The Terms Of The Agreement.

There is no genuine issue of material fact that Par would not have been able to launch any generic product on January 1, 2021 in the absence of the Agreement. Par did not obtain FDA approval of its ANDA until June 2022,[195] more than a year ***after*** the licensed entry date. DPPs narrowly avoided dismissal because the Court took as true DPPs' allegation that Par was "not

(Liu Rep.) ¶ 98. Even so, Dr. Davitz failed to include any analysis of these patents in his reply report. SOF ¶ 102; *see also generally* Ex. 78B (Davitz Reb.).

[191] SOF ¶¶ 103-15.

[192] SOF § IX.E (¶¶ 96-115). It is undisputed that after settling its Hatch-Waxman Litigation with Par, Sucampo later asserted the '481 and/or '187 Patents (among other patents) against later ANDA filers Teva, Sun, and Zydus, none of whom was successful at proving any of these claims not infringed, invalid or unenforceable. SOF § IX.D (¶¶ 93-95); *see also* Ex. 20 (Teva Patent Litig., Compl.) at ¶¶ 15, ¶¶ 51-58; Ex. 117 (Sun Patent Litig., Compl.), ¶¶ 17, 50-57; Ex. 118 (Zydus Patent Litig., Compl.), ¶¶ 11, 30-37; Exs. 16, 17, and 18 (Civil Docket Sheets for Teva, Sun and Zydus litigations).

[193] *See Wellbutrin*, 868 F.3d at 165; *Nexium*, 842 F.3d at 62-63; *Humira*, 465 F. Supp. 3d at 844.

[194] *Wellbutrin*, 868 F.3d at 169; *see also Humira*, 465 F. Supp. 3d at 844-46; *Revlimid*, 2024 WL 2861865, at *84.

[195] SOF ¶ 186.

motivated to pursue its own ANDA" due to the "option to launch an AG" under the Agreement.[196] But there is no evidence that Par intentionally dragged its feet in seeking approval of its ANDA. Instead, Par's testimony and contemporaneous statements among Par, its partners, and FDA confirm Par's intentions to obtain approval as soon as possible. Plaintiffs thus cannot meet their burden of showing their claimed injury was caused by the Agreement.

Plaintiffs strategically narrowed discovery from the non-party ANDA Filers (including from alleged co-conspirator, Par), including avoiding Rule 30(b)(6) testimony on key issues like Par's will and means to obtain, FDA approval. As a result, Plaintiffs can proffer no evidence that Par intentionally delayed FDA approval, that Par had any financial incentive to do so, or that FDA did, or had any reason to, stall its review of Par's ANDA. Plaintiffs offer only the speculation of their pharmacology expert, Dr. Uwe Christians—a professor who has never worked at FDA and has [redacted][197]— that Par's motivation to obtain FDA approval was undermined by the Settlement Agreement and that Par took the "easy way" out by distributing AG product from Sucampo *in lieu* of pursuing FDA approval of its ANDA. As further addressed in Takeda's Motion to Exclude certain expert testimony on this point, Plaintiffs' experts cannot opine about Par's intentions and state of mind, leaving Plaintiffs with nothing to counter direct evidence of Par's diligence and motivations, and the legitimacy of FDA's demands.

Plaintiffs bear the burden of proving that the alleged anticompetitive effect of the Settlement was the "material cause" of their alleged injury.[198] It is "beyond fair dispute" that a regulatory bar to generic launch can "break the chain of causation."[199] Plaintiffs cannot surmount

[196] Order on Mot. to Dismiss, C.A. No. 21-11255, ECF No. 41 (D. Mass. Dec. 27, 2020), at 8.
[197] Ex. 74 (Christians Tr.), at 323:18-22.
[198] *Solodyn*, 2018 WL 563144, at *13 ("In an antitrust case, plaintiffs must demonstrate that the antitrust violation was a 'material cause' of their injury."); *accord Nexium*, 42 F. Supp. 3d at 266.
[199] *Wellbutrin*, 868 F.3d at 165 (affirming summary judgment); *accord Nexium*, 42 F. Supp. 3d at 268 ("injuries that are caused almost exclusively by the actions of a government regulators do not give rise to antirust liability").

this causal hurdle "where there is insufficient proof [or plausible allegations] of causation, or where the intervening conduct was independently caused by [FDA]."[200] Here, it was the intervening lack of FDA approval that was the "material cause"[201] of Par not launching its own Amitiza ANDA product prior to the license effective date in the Settlement; Plaintiffs cannot prove that, but-for the Agreement, Par would have obtained regulatory approval sooner than it did—*e.g.*, as early as October 2016, April 2018, or later in 2018-2019, across Plaintiffs' but-for "scenarios" 1-3.[202] "[E]valuating the question of an earlier ANDA approval . . . requires the Court to guess what FDA would have done had the launch date for [the generic] been different," and "[g]uesswork does not create a genuine issue of material fact."[203] "Guesswork" is all Plaintiffs have.

Direct evidence of Par's post-settlement activity demonstrates that Par continued to doggedly pursue final FDA approval despite many regulatory obstacles. Par's representative testified that Par continued to pursue FDA approval of its ANDA for a generic lubiprostone product, notwithstanding the fact that it had a right to launch an AG under the Settlement Agreement.[204] Contemporaneous statements by Par and its partners also demonstrate Par's conviction. Following FDA's findings of current good manufacturing practices ("cGMP")

[200] *Nexium*, 42 F. Supp. 3d 231 at 266-79 (granting summary judgment on causation grounds where "Plaintiffs have offered little evidence in support of their complicated, multi-step proposition that the FDA would have approved Ranbaxy's generic Nexium any earlier than May 2014 in the absence of this settlement agreement"), *aff'd*, 842 F.3d 34 (1st Cir. 2016); *see also, e.g., Lipitor*, 2024 WL 2866654, at *2 (granting summary judgment where "Plaintiffs have failed to create a genuine issue of material fact that it was more likely than not that FDA would have completed its review any sooner and approved Ranbaxy's generic drug manufacturer's ANDA earlier than Nov. 30, 2011 [the license effective date of the challenged settlement]"); *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 265-67 (D. Mass. 2017) (granting motion to dismiss); *Solodyn*, 2015 WL 5458570, at *9 (granting motion to dismiss); *Bristol-Myers Squibb Co. v. Copley Pharm. Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (dismissing antitrust counterclaim because "[w]ithout tentative FDA approval, [counterclaim plaintiff] could not now enter the market, regardless of the pending [patent] litigation").

[201] *See Solodyn*, 2018 WL 563144, at *13.

[202] Ex. 75A (Clark Report) ¶ 15.C; Ex. 84A (Leffler Report) ¶ 13.E-F.

[203] *Lipitor*, 2024 WL 2866654, at *27.

[204] SOF ¶ 126 (she was asked [redacted]

deficiencies at the facility of Par's lubiprostone API supplier, Everlight, in 2015, [redacted][205] Everlight documents recount [redacted][206] Later, in March 2021 (*i.e.*, just after the License Effective Date), Everlight personnel recounted that '[redacted][207] There is no evidence that counters or contradicts this direct evidence of Par's intent to pursue final approval of its ANDA long after entering into the Settlement Agreement in 2014.[208]

The extensive record of Par's correspondence with FDA also demonstrates Par's uninterrupted "will," but lack of a "way"[209] given FDA's requirements. As summarized in the attached **Table A**, from 2014 into 2022, Par and its partners responded to serial guidance and demands by FDA, including: at least seven complete response letters ("CRL")[210]; FDA's responses to multiple requisite amendments, minor and major, to Par's ANDA; various information requests, including requests directed to the relevant DMF;[211] a revised FDA Product Specific Guidance ("PSG") for lubiprostone; and requests stemming from FDA's inspectional findings for ECIC's

[205] *Id.* ¶ 162.
[206] *Id.* ¶ 176.
[207] *Id.* ¶ 179 (emphasis added). This further corroborates Takeda's understanding that the declining royalty provisions only applied if Par launched its ANDA product and did not come to market with a Sucampo-supplied AG. *See* § I.A, *supra*.
[208] Plaintiffs' expert, Dr. Christians, admitted as much, testifying that [redacted] Ex. 74 (Christians Tr.), at 260:8-18; 261:19-262:8.
[209] *See Nexium*, 42 F. Supp. 3d at 270.
[210] A CRL is communication to an applicant from FDA "usually describing all of the deficiencies that the Agency has identified in an NDA or ANDA that must be satisfactorily addressed before it can be approved." 21 C.F.R. § 314.3.
[211] A DMF—drug master file—is a submission to FDA by the DMF holder to be used for certain purposes. ECIC was the drug substance DMF holder and Par relied on this DMF. SOF ¶ 139.

drug manufacturing facilities. Par also made multiple requests for "priority review" of its ANDA.

Par did not launch generic Amitiza prior to January 2021 because FDA was not satisfied that Par's ANDA, including the DMF on which it relied, met all final approval requirements.[212] This regulatory barrier breaks any alleged causal chain between the Agreement and Par's failure to launch generic Amitiza before January 2021.[213]

It is not surprising that Par continued its efforts to obtain FDA approval despite having the option to market an AG. The Settlement Agreement incentivized Par to get FDA approval of its ANDA because [redacted].[214] The terms of the Agreement also provided no guarantees that Par (while it was the first ANDA filer) would be the first generic to enter the market on January 1, 2021. For example, Par's eligibility for 180-day exclusivity as the first filer could be forfeited, [redacted].[216] The unrefuted testimony of Par's designated representative shows that Par was well aware that there were "several situations where a third party, Sucampo or Takeda, could launch a generic or an authorized generic before January 1, 2021."[217] Par understood that [redacted]

[212] SOF ¶¶ 138-86.
[213] *See Wellbutrin*, 868 F.3d at 165; *Nexium*, 42 F. Supp. 3d at 268.
[214] *See* § I.A, *supra*.
[215] The FD&C Act provides for a number of conditions under which an ANDA applicant may forfeit eligibility for 180-day exclusivity, including failure to market, failure to obtain tentative approval, withdrawal of the application, among others. § 505(j)(5)(D) of the FD&C Act; FDA Guidance for Industry, 180-Day Exclusivity: Questions and Answers (Draft) (Jan. 2017) at 4, https://www.fda.gov/media/102650/download.
[216] *See* SOF ¶¶ 152; Ex. 13 (2014 Par Settlement) §§ 1.1 (defining "License Effective Date" and "Market Decline Event"), 3.6, 3.7, 3.10, 3.11.
[217] SOF ¶ 152.

[redacted][18] That is because the Settlement Agreement provided that [redacted][219] Accordingly, not only did Par pursue approval of its ANDA diligently following the Settlement, the terms of the Settlement Agreement itself motivated Par to do so.

In response to this direct evidence, Plaintiffs rely only on improper speculation about Par's alleged lack of motivation and intent to pursue FDA approval because Plaintiffs made the tactical decision not to develop any evidence of Par's actual post-settlement intent. Specifically, Plaintiffs: (i) dropped, by agreement, their request for Rule 30(b)(6) testimony from Par about its "regulatory files for [Par's] Generic Amitiza ANDA . . . [and] all planning or prioritization documents concerning questions or comments from FDA;" (ii) [redacted][220] The only rational explanation for such gamesmanship is that Plaintiffs wanted their experts to fill that void with their own speculative opinions about what Par was doing (or not doing) to pursue ANDA approval and why. It is well-settled that summary judgment "cannot be defeated by relying on improbable inferences, conclusory allegations, or rank speculation,"[221] and certainly not by "ignorance of the facts."[222]

The result of Plaintiffs' carefully tailored discovery is a lack of any direct or even circumstantial evidence that Par or FDA slowed their work to prosecute Par's ANDA, or that either was incentivized to do so. For example, there is no evidence that Par chose to distribute an Amitiza

[218] *Id*.
[219] *Id.*; Ex. 13 (2014 Par Settlement) §§ 1.1, 3.12.
[220] SOF ¶¶ 120-28.
[221] *Ingram v. Brink's, Inc.*, 414 F.3d 222, 228–29 (1st Cir. 2005) ("summary judgment can be entered even where ambiguous, often murky concepts such as motive and intent are involved").
[222] *Genzer v. James River Ins. Co*., 934 F.3d 1156, 1160 (10th Cir. 2019) (affirming summary judgment).

AG under the Settlement Agreement to the detriment of its pursuit of regulatory approval and launch of its own ANDA product.[223] There is also no evidence that Par stood ***to gain anything*** by pursuing an AG distribution under the Settlement Agreement to the exclusion of launching its own ANDA product.[224] The only counterfactual "evidence" Plaintiffs have presented is the speculative opinions of their experts, Dr. Christians and Mr. Clark, that Par delayed approval efforts due its ability to instead distribute an AG under the Agreement because that was the "easy way."[225] Such purported "evidence" amounts to nothing more than inadmissible, "arrant speculation, optimistic surmise or farfetched inference,"[226] and, thus, "cannot defeat a motion for summary judgment."[227]

As set forth in Takeda's accompanying Motion to Exclude, Dr. Christians' and Mr. Clark's opinions do not satisfy Rule 702. Indeed, Plaintiffs' expert charged with assessing the "urgency" of Par's efforts to gain FDA approval, Dr. Christians, unequivocally stated [redacted]

[223] *Contrast Nexium*, 42 F. Supp. 3d at 270 (finding an issue of fact, although "far from conclusive," regarding a generic filers "willingness" to get approval and launch its ANDA product prior to the agreed entry date given testimony from the generic that it "saw no need to proceed with generic Nexium preparatory strategies at an earlier time"). There is no such evidence here.

[224] *See* Ex. 74 (Christians Tr.) 259:13-260:21 [redacted]. Ex. 75B (Clark Rebuttal) ¶ 65. Mr. Clark provides no analysis, representative examples, or accounting for the range of factors that one would consider for this "2 for 1" approach to drug development. His opinion on this point should not be considered.

[225] Ex. 74 (Christians Tr.) 256:24-258:4; *see also, e.g.,* Ex. 73A (Christians Report) ¶ 26.iii [redacted]); Ex. 73B (Christians Rebuttal) ¶ 60 [redacted]"); Ex. 75A (Clark Report) ¶ 67 ([redacted]).

[226] *Kelly v. United States*, 924 F.2d 355, 357 (1st Cir. 1991).

[227] *Virgin Atl.*, 69 F. Supp. 2d at 579 (quoting *Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1198 (3d Cir. 1995) (alteration in original)); *see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 242 (1993) (expert opinion cannot support a jury verdict when it "is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable").

[redacted][228] Similarly, Mr. Clark admitted that [redacted][229, 230] In contrast, Takeda's generics expert, Mr. Patel, offered unrefuted testimony [redacted][231]

Nor is there any evidence that FDA deprioritized or intentionally slowed its review of Par's ANDA following Par's agreement to a 2021 licensed entry date. Rather, Plaintiffs' experts merely speculate about FDA's intentions.[232] Such speculative opinions, not grounded in facts, are entirely improper and must be excluded as further addressed in Takeda's Motion to Exclude certain opinions of Dr. Christians and Mr. Clark. While Plaintiffs will no doubt argue that FDA *could* have acted differently or *could* have been more motivated to accelerate the approval of Par's ANDA absent the Settlement Agreement, summary judgment is warranted where, as here, there is "little evidence that the agency *would have* given final approval to the [generic's] ANDA"

[228] Ex. 74 (Christians Tr.) 264:5-15 [redacted]

[229] Ex. 76 (Clark Tr.), 315:9-19; 319:8-320:15; 328:11-23; 332:13-333:10.

[230] Plaintiffs' experts point to [redacted] Ex. 75A (Clark Report) ¶ 108. Par's representative, Ms. Calabro, was clear, however, that such [redacted] Ex. 72 (Calabro Tr.), at 102:2-103:1; 109:9-110:15; 116:9-117:12. With that context, Plaintiffs' speculation about Par's intent based on cherry-picked entries in an informal "launch tracker" document can hardly defeat summary judgment. *See Nexium*, 42 F. Supp. 3d at 266, 271-79 (granting summary judgment due to lack of regulatory approval despite the first ANDA filer "chang[ing] [post-settlement] its projections to commercially market its generic Nexium to May 2014 [the agreed licensed entry date]," where such dates were just "placeholder dates").

[231] Ex. 92A (Patel Report) ¶¶ 101-104.

[232] *See, e.g.*, Ex. 74 (Christians Tr.) 222:9-223:18, 230:7-232:16.

sooner.[233] Speculative "guesswork" that FDA would have worked toward an earlier date for approval of Par's ANDA absent the Agreement cannot demonstrate causation at summary judgment, and amounts to mere "appeals to 'metaphysical doubt[s] as to material facts.'"[234]

In sum, because Plaintiffs cannot counter evidence unequivocally demonstrating that lack of FDA approval of Par's ANDA was *the* reason Par could not have launched its own product sooner, the "causal chain" between the Agreement and Plaintiffs' alleged harm has been broken.

C. There Is No Evidence The ANDA Filers Would Have Been Ready And Able To Launch At The Times Assumed By Plaintiffs

Takeda is also entitled to summary judgment on causation because there is no admissible evidence that the ANDA Filers would have been (but for the Agreement) able to produce and launch sufficient quantities of their own generic Amitiza products at the times Plaintiffs' experts assume. Plaintiffs allege that the ANDA Filers would have launched their own generic Amitiza products sooner than they actually did (if they ever did) as follows:

Filer	FDA Approval[235]	Actual Launch / Distribution[236]	Product[237]	Earliest Alleged But-For Launch[238]
Par	6/27/22	1/21	Sucampo Amitiza AG	10/1/16
Teva	1/18/22	1/23	Own Generic Amitiza	3/21
Amneal	11/30/21	1/23	Own Generic Amitiza	6/19/19
DRL	2/8/22	1/23	Sucampo Amitiza AG	2/8/22

[233] *Nexium*, 42 F. Supp. 3d at 277-78 (granting summary judgment on grounds that lack of regulatory approval broke "causal links" between alleged harm and an ANDA litigation settlement and holding that summary judgment is warranted where there is "little evidence that the agency *would have* given final approval to the [generic's] ANDA," even where reasonable interferences can be drawn that FDA *could have* been "concerned about the possibility of a regulatory bottleneck for generic [entry]" or "motivated" to grant swifter approval.) (emphasis added).
[234] *Lipitor*, 2024 WL 2866654, at *29 (quoting *Matsushita*, 475 U.S. at 586).
[235] SOF ¶¶ 186, 190, 195, 200.
[236] *Id.*, ¶¶ 28, 189, 193, 198; Ex. 96A (Saravia Report), ¶ 45.
[237] SOF ¶¶ 28, 66.
[238] Ex. 75A (Clark Report) ¶¶ 15.C-D; Ex. 89A (Marchetti Report) ¶ 18.b.

Each of Plaintiffs' presumptive but-for launch dates hinges on a series of speculative assumptions. One, addressed above, is the faulty assumption that Par would have achieved FDA approval much sooner had it not been "de-motivated" by the Agreement. Another key assumption is that each ANDA Filer would have been able and ready to sell launch quantities of their own generic Amitiza by the dates Plaintiffs assume—several of which pre-date the Filer's actual launch ***by years***. There is no evidence to support these "launch readiness" assumptions beyond the speculation of Plaintiffs' expert, Ms. Susan Marchetti. She opines that [redacted].[239] As set forth in Takeda's accompanying Motion to Exclude, Ms. Marchetti's opinions are speculative, lack adequate factual support, and are impermissibly informed by a pre-determined outcome she was asked to "assume."

"Plaintiffs bear the burden of evincing evidence that would enable a reasonable jury to find each core element of an antitrust claim — including causation."[240] Having alleged that, absent the Agreement, generic Amitiza would have been available sooner, Plaintiffs must prove that Par and the other ANDA Filers *would have* overcome all "hurdles" to enter the market.[241] As part of that inquiry, Plaintiff must prove that the ANDA Filers had the means (*i.e.*, the "will" and the "way") to make and sell launch quantities of generic Amitiza by the dates Plaintiffs assume and that the ANDA Filers *would* have done so.[242] As the Third Circuit explained in *Wellbutrin* when affirming summary judgment on causation grounds, "it is not enough for the [plaintiff] to show that [the

[239] *See, e.g.*, Ex. 89A (Marchetti Report) ¶¶ 75, 93, 101, 113; Ex. 90 (Marchetti Tr.) 192:18-23.
[240] *Nexium*, 42 F. Supp. 3d at 287; *see also* Hovenkamp, Herbert, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 Minn. J.L. Sci. & Tech. 3, 23-24 (2014) ("What the *Actavis* majority stated was that the presumptions continue to lie with the defendant, thus giving the plaintiff the burden of proof . . .").
[241] *Nexium*, 42 F. Supp. 3d at 269; *see also Intuniv*, 496 F. Supp. 3d at 671-77 (addressing at summary judgment the alleged will and ability of alleged generic co-conspirator to launch generic product at-risk).
[242] *Nexium*, 42 F. Supp. 3d at 270; *see also Wellbutrin*, 133 F. Supp. 3d at 767-68 .

generic] wanted to launch its drug."[243] "[T]o withstand summary judgment, the [plaintiffs] must produce evidence from which a reasonable jury could conclude that it is more likely than not that [the generic] *would* have" launched, "[e]vidence showing that [the generic] *may* have been able to [launch] does not meet that standard."[244] On this issue, Plaintiffs face a stark failure of proof.

As they did with their discovery of Par (discussed above), Plaintiffs strategically narrowed their discovery of the non-party ANDA Filers. Plaintiffs' production / supply chain expert, Ms. Marchetti, testified that [redacted][245]

Plaintiffs did not, however, collect ***any*** of that information (or at least did not provide it to Ms. Marchetti) from the ANDA Filers.[246] Plaintiffs also opted not to pursue ***any*** testimony from the ANDA Filers regarding their generic Amitiza manufacturing capabilities, launch readiness, or factors affecting the timing of a launch.[247] While Plaintiffs' subpoena to Par sought Rule 30(b)(6) testimony on "[Par's] launch planning . . . including documents sufficient to show [Par's] commercial manufacturing scaleup, launch build timeline, compliance status, capacity, and prioritization level," Plaintiffs dropped that topic and objected to Takeda's efforts to elicit testimony on the same matters.[248] Plaintiffs also agreed to truncate DRL's Rule 30(b)(6) testimony, and did not elicit any testimony from Teva or Amneal.[249] Plaintiffs' strategically limited inquiry resulted in an absence of the evidence they require to present a triable issue of fact.

[243] *Wellbutrin*, 868 F.3d at 165-67.
[244] *Id.*
[245] Ex. 90 (Marchetti Tr.) 88:8-15; 89:5-18; 90:7-16; 91:5-95:16; 97:10-103:9.
[246] SOF ¶¶ 129-31, 134-37, 139-41, 145-47, 151-53.
[247] *Id.* ¶¶ 116-19, 134-36, 143-44, 149-50.
[248] *Id.* ¶¶ 116-24. Indeed, presumably for this reason Ms. Marchetti ***was not even aware*** that two Par representatives were deposed. Ex. 90 (Marchetti Tr.) 126:3-6.
[249] SOF ¶¶ 129-31, 134-37.

Absent any actual proof of the ANDA Filer's capacity to make generic Amitiza and on what schedule, Plaintiffs' claims hinge on Ms. Marchetti's opinions. But they are inadmissible for several reasons as set forth in Takeda's accompanying Motion to Exclude. First, her "method" was outcome-oriented and rooted in a misconception of Plaintiffs' burden. Inexplicably, Ms. Marchetti was asked by Plaintiffs' counsel to [redacted].[250] This is impermissible. When an expert simply assumes the desired outcome—and therefore works *backwards* to form her opinions—that opinion is inadmissible.[251] Just as puzzling was Ms. Marchetti's implicit burden-shifting whereby she relied (in the absence of any affirmative proof) on her own surmise that [redacted].[252] Such an opinion cannot satisfy Plaintiffs' burden of affirmatively proving that, absent the Agreement, the ANDA Filers had the means and would have launched their own generic Amitiza products sooner. Courts have rejected out-of-hand attempts to "re-cast longstanding causation requirements as an affirmative defense."[253]

Second, because of Plaintiffs' choice to limit their discovery of non-party ANDA Filers, Ms. Marchetti had none of the information she unequivocally testified she would need to analyze a company's capacity to make a drug, in what volumes, and on what schedule. Ms. Marchetti [redacted].[254] [redacted]

[250] Ex. 90, (Marchetti Tr.) 22:5-12.
[251] *See, e.g.*, *Rodriguez v. Hosp. San Cristobal, Inc.*, 91 F.4th 59, 72 (1st Cir. 2024) (affirming exclusion of expert opinion where nothing in the record supported ultimate assumption).
[252] *See, e.g.,* Ex. 90, (Marchetti Tr.) 192:15-23.
[253] *Nexium*, 42 F. Supp. 3d at 287 (rejecting Plaintiffs' attempt at summary judgment to shift the burden of proof onto the defense for causation issues, including but-for launch readiness).
[254] Ex. 90 (Marchetti Tr.) 88:8-15; 89:5-18; 90:7-16; 91:5-95:16; 97:10-103:9; 130:10-140:5 (regarding Par); 160:18-163:16 (Amneal); 181:9-186:14 (Teva); 217:17-223:2 (DRL).

[redacted][256][redacted][257] A bedrock principle in vetting expert testimony is whether the information the expert relies upon "was ***consistent with the standards of the expert's profession***."[258] Ms. Marchetti's opinions fall woefully shy of that mark and should be excluded.

Especially after accounting for the inadmissibility of Ms. Marchetti's' proffered opinions, Plaintiffs can make no evidentiary showing that the ANDA Filers had the capacity to make generic Amitiza in launch quantities by the dates on which Plaintiffs assume they could in the but-for world. That failure breaks the causal chain between the Agreement and the allegedly delayed timing of Par's launch and must result in summary judgment.

V. THE GENERIC-ONLY AND BRAND-ONLY PURCHASERS DID NOT SUFFER ANY INJURY AND LACK STANDING TO PURSUE THEIR CLAIMS

A. Thirteen DPP Class Members Purchased Only AG Amitiza Product From Third Parties And Thus Lack Antitrust Standing Under *Illinois Brick*.

Under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), only direct purchasers from the antitrust violator have standing to bring an antitrust claim. At the motion to dismiss stage, this Court dismissed claims "premised on generic sales," holding that "because plaintiffs have dismissed their claims against Par, the 'selling member of the alleged antitrust conspiracy' is no

[255] *Id.* at 129:17-25 (regarding Par); 156:3-10, 159:12-160:14 (Amneal); 179:4-17, 180:8-20, 181:2-8 (Teva); 200:13-203:9 (DRL).
[256] *Id.* at 141:7-22 (regarding Par); 167:3-18 (Amneal); 186:15-187:5 (Teva); 223:3-18 (DRL).
[257] *Id.* at 141:23-142:11 (regarding Par); 167:19-168:9 (Amneal); 187:6-21 (Teva); 223:19-224:8 (DRL).
[258] *SMS Sys. Maint. Svs., Inc. v. Digital Eq. Co.*, 188 F.3d 11, 25 (1st Cir. 1999) (emphasis added).

longer a defendant in the action, thereby eliminating *Illinois Brick* standing" for purchasers from Par.[259] That same logic applies to thirteen members of the putative DPP class: these class members purchased only AG Amitiza product from Dr. Reddy's Laboratories ("DRL"), Sun, or one/both of them and Par during the proposed class period.[260] Like Par, DRL and Sun purchased and resold AG Amitiza product manufactured by Sucampo, rather than selling their own generic product.[261] Thus, like Par, DRL and Sun were simply ***distributors*** of Sucampo's AG Amitiza product, and any proposed class member that purchased only AG from them was an *indirect* purchaser. These purchasers lack standing to bring their antitrust claims, as this Court already determined with respect to Par purchasers.[262] Takeda should be granted summary judgment on the claims of those thirteen putative members of the proposed DPP class.

B. The Brand-Only Purchasers Lack Constitutional Standing Because DPPs Fail To Show That They Suffered An Injury-In-Fact

"[T]o have Article III standing to sue in federal court, a plaintiff must show, among other things, that the plaintiff suffered concrete injury in fact." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 414 (2021). The putative DPP class is defined to include ten members that purchased only brand Amitiza, and accordingly suffered no injury. These entities include: (1) three brand-only purchasers who purchased only brand Amitiza throughout the class period—including *after* Par's entry in 2021;[263] and (2) seven brand-only purchasers who ceased purchases of brand Amitiza prior to Par's distribution of an AG in January 2021, and did not make *any* purchases of brand or generic

[259] ECF No. 61, Memorandum and Order on Defendants' Motion to Dismiss dated Dec. 27, 2022, at 11-12 ("MTD Order").
[260] These class members are: Alpine Health LLC, Bluepax Pharmaceuticals, CityMedRx LLC, CVS, Guardian Pharmacy, Hospital Pharmaceutical Consulting, Hygen, independent Pharmacy Cooperative, Keysource Medical, NDC Distributors LLC, Oak Drugs Inc., and Primed Pharmaceuticals. *See* SOF ¶ 65.
[261] SOF ¶ 66.
[262] MTD Order at 12.
[263] Ex. 96 (Saravia Report), ¶ 31.

Amitiza thereafter.[264] DPPs cannot show that these purchasers were injured because their injury depends on purchasing generic Amitiza at a lower price, which they never did.

DPPs put forward two theories of injury in fact: *first*, that purchasers of brand Amitiza prior to generic entry would have switched to cheaper generic Amitiza if it was available, and *second*, that purchasers of generic Amitiza would have been able to obtain it at a lower price if it had been available earlier.[265] DPPs notably do not allege or prove that brand Amitiza would have been cheaper absent the alleged conduct. Whether or not putative class members suffered an injury, then, depends on the assumption that they would have purchased generic Amitiza in the but-for world. But there is no evidence that, contrary to their real world practices, they would have done so. Again, three of these ten putative class members did not buy generic Amitiza *even when it was available*, showing that they *would not have bought* generic Amitiza in the but-for world either. And Plaintiffs have no evidence to suggest that the remaining seven brand-only purchasers would have bought brand or generic Amitiza in the but-for world after having completely ceased buying *any* Amitiza (brand or generic) before Par's AG launch on January 1, 2021.[266]

Nor are DPPs correct, as they suggested in class certification briefing, that "injury is complete at the time the brand purchase is made."[267] This is only true *if* an entity purchased at a higher price in the actual world than they would have in the but-for world.[268] The problem, though, is that DPPs cannot show that brand-only purchasers purchased at a higher price in the actual world relative to the but-for world, *i.e.*, that they suffered any overcharge in the first place. DPPs' theory that these purchasers paid overcharges simply because they bought brand Amitiza, regardless of

[264] Ex. 96 (Saravia Report), ¶ 32.
[265] *See* Ex. 77A (Conti Report), ¶ 79.
[266] *See generally* Defs.' Opp'n to DPPs' Mot. for Class Certification, ECF No. 292, at 26-29.
[267] DPPs' Reply in Supp. of Class Certification, ECF No. 319, at 16.
[268] *See Illinois Brick*, 431 U.S. 720; *Am. Sales Co., LLC v. Pfizer, Inc.*, No. 2:14CV361, 2017 WL 3669604, at *8 (E.D. Va. July 28, 2017), *R. & R. adopted*, 2017 WL 3669097 (Aug. 24, 2017).

whether they would have bought generic Amitiza at a lower price in the but-for world, is insufficient because "Article III standing requires a concrete injury even in the context of a statutory violation." *TransUnion*, 594 U.S. at 426.

VI. PLAINTIFFS CANNOT RECOVER CERTAIN DAMAGES BECAUSE THEY FAIL TO PLEAD OR PROVE FRAUDULENT CONCEALMENT.

Federal antitrust claims are subject to a four-year statute of limitations. 15 U.S.C. § 15b. Claims accrue under the Sherman Act upon an injury traceable to the defendant's conduct.[269] When, as here, Plaintiffs allege continuing violations (*i.e.*, repeated overcharges), they can recover only for alleged violations within four years of their initial complaint,[270] with Takeda bearing the initial evidentiary burden, which shifts to Plaintiffs to show that the statute of limitations does not apply. *Ouellette v. Beaupre*, 977 F.3d 127, 135 (1st Cir. 2020).

DPPs filed their first complaint on June 25, 2021.[271] EPPs filed their complaint on November 30, 2023.[272] And Retailers filed their complaints on December 13, 2023 and January 29, 2024.[273] Because Plaintiffs cannot recover damages for alleged injuries that pre-date their complaint by more than four years, DPPs and Retailers (who were unnamed members of the putative DPP class) can recover for overcharges only after June 25, 2017, and EPPs can recover for damages only after November 30, 2019.[274]

Plaintiffs invoke the doctrine of fraudulent concealment, claiming that they are entitled to damages on purchases beyond four years before their complaints were filed.[275] The statute of

[269] *See In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 61 (D. Mass. 2003); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 399 (D. Mass 2013).
[270] *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14–MD–02503–DJC, 2015 WL 5458570, at *8 (D. Mass. Sept. 16, 2015).
[271] Direct Purchaser Plaintiffs' Initial Consolidated Class Action Complaint, ECF No. 1 ("DPP Compl.").
[272] End Purchaser Plaintiffs' Class Action Complaint, ECF No. 1 ("EPP Compl.").
[273] Complaint of Walgreen Co., The Kroger Co., Albertsons Companies, Inc. and H-E-B, L.P., ECF No. 1 ("Retailer Compl."); Complaint of CVS Pharmacy, Inc., ECF No. 1 ("CVS Compl.").
[274] *See Solodyn*, 2015 WL 5458570, at *8.
[275] DPP Compl., ECF No. 28, ¶ 316; EPP Compl., ECF No. 1, ¶ 230; Retailer Compl., ECF No. 1, ¶ 200.

limitations can be tolled under the doctrine of fraudulent concealment when a plaintiff shows "1) wrongful concealment by defendants of their actions; and 2) failure of the claimant to discover, within the limitations period, the operative facts which form the basis of the cause of action; 3) despite the claimant's diligent efforts to discover the facts."[276] "The burden rests squarely on the party pleading fraudulent concealment." *Berkson v. Del Monte Corp.*, 743 F.2d 53, 55 (1st Cir. 1984). "Silence or passive conduct on the part of the defendant is not deemed fraudulent, unless the relationship of the parties imposes a duty upon the defendant to make disclosure."[277] In reverse payment actions, courts have rejected assertions of fraudulent concealment when the material terms of the settlement have been disclosed.[278]

Under the doctrine of fraudulent concealment, Plaintiffs seek damages beginning at hypothetical alternative entry dates as early as October 2016.[279] They allege "[t]hat Takeda and Sucampo paid Par in the form of a functional no-authorized generic promise (or 'one generic only' agreement)," a scheme that "was not fully revealed until after Par launched its authorized generic" and Takeda did not launch one.[280] Specifically, Plaintiffs allege that the October 9, 2014 press release announcing the Settlement was misleading because it noted the non-exclusive AG license and failed to disclose the declining royalty, which Plaintiffs claim constituted a "functional" no-AG agreement.[281] But Plaintiffs concede that the press release disclosed a "profit split" and that

[276] *Alvarez-Mauras v. Banco Popular of P.R.*, 919 F.3d 617, 626 (1st Cir. 2019); *see also Berkson*, 743 F.2d at 55.
[277] *DJ Mfg. Corp. v. Tex-Shield, Inc.*, 275 F. Supp. 2d 109, 122 (D.P.R. 2002).
[278] *See In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, 172 F. Supp. 3d 724, 744-45 (D.N.J. 2016) (no tolling where defendants "made public filings with the SEC and issued press releases that, though they did not include the *full* terms of the settlement, did disclose material facts sufficient to inform [p]laintiffs of the nature of their claims, or at least to allow them to discover the claims with reasonable diligence"); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 748 (E.D. Pa. 2014) (no tolling where defendants had "affirmatively disclosed" material terms).
[279] *See* Ex. 77A (Conti Report) ¶ 76.
[280] DPP Compl., ECF No. 28, ¶ 316; *see* EPP Compl., ECF No. 1, ¶¶ 234-235; Retailer Compl., ECF No. 1, ¶ 200; CVS Compl., ECF No. 1, ¶ 197.
[281] DPP Compl., ECF No. 28, ¶ 321; Retailer Compl., ECF No. 1, ¶ 149; CVS Compl., ECF No. 1, ¶ 147; EPP Compl., ECF No. 1, ¶¶ 177-78.

the profit split "implies, but does not necessarily mean, a 50/50 division."[282] Plaintiffs' experts have now put forth the theory that the 50/50 division of profits was itself a no-AG agreement, independent of the declining royalty.[283] Consequently, Plaintiffs had knowledge of the material facts underlying their theory—*i.e.*, that the 50/50 "profit split," irrespective of any decline, was a reverse payment—back in 2014. EPPs concede that they were on notice of their pending claims as of January 2021, when Takeda did not launch an AG product.[284] In any event, as this Court found in ruling on Takeda's motion to dismiss EPPs' complaint, Plaintiffs fail to allege a failure to discover operative facts despite diligent efforts.[285]

As an initial matter, Plaintiffs fail to show wrongful concealment because Takeda had no duty to disclose.[286] Second, Plaintiffs cannot claim the "functional no-authorized generic promise" was concealed when the terms of the Agreement that Plaintiffs claim constituted actionable conduct were disclosed in a press release. As of the 2014 press release, Plaintiffs had "material facts sufficient to inform [p]laintiffs of the nature of their claims, or at least to allow them to discover the claims with reasonable diligence." *Lamictal*, 172 F. Supp. 3d at 744–45. As a result, the limitations period should not be tolled. DPPs' and Retailers' recovery should be limited to sales after June 25, 2017, within four years of the filing of DPPs' complaint, and EPPs can only recover damages after November 30, 2019 (four years before they filed their initial complaint).

VII. CONCLUSION

For the foregoing reasons, Takeda respectfully requests that the Court grant Takeda's Motion for Summary Judgment for all of Plaintiffs' claims.

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[282] DPP Compl., ECF No. 28, ¶ 321; Retailer Compl., ECF No. 1, ¶ 149; CVS Compl., ECF No. 1, ¶ 147; *see also* EPP Compl., ECF No. 1, ¶ 178.
[283] Ex. 94B (Ruhm Rebuttal) ¶ 40, Figure 2; Ex. 84B (Leffler Rebuttal) ¶ 58.
[284] EPP Compl. ¶¶ 234-35.
[285] R. & R. on Mot. to Dismiss EPPs' Compl., ECF No. 289, at 71.
[286] *See DJ Mfg.*, 275 F. Supp. 2d at 122.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Joshua S. Barlow, hereby certify that on November 19, 2024, I caused a true and accurate copy of the above document, filed with the Court, to be served upon counsel of record for each party via the Court's ECF filing system or, for sealed versions of the filing, via electronic mail.

/s/ *Joshua S. Barlow*
Joshua S. Barlow

TABLE A

PAR'S EXEMPLAR MATERIAL COMMUNICATIONS WITH FDA

2014 – 2022

- [redacted];
- [redacted];
- FDA's review of Par's "minor" amendment to its ANDA submitted in September 2014 resulting from Par's response to FDA's March 2014 CRL;
- [redacted];
- [redacted];
- [redacted];
- FDA's July 17, 2015 issuance of a revised Product Specific Guidance ("PSG") for lubiprostone containing new guidance on methods to establish bioequivalence;
- [redacted]
- [redacted]
- [redacted];
- [redacted];
- [redacted];
- [redacted];
- [redacted];

TABLE A

- [redacted]
- [redacted]
- [redacted]; and
- [redacted]

[1] SOF ¶¶ 147-50, 153-84.